* These are unofficial translations. Only the original Japanese texts of the laws and regulations have legal effect, and the translations are to be used solely as reference material to aid in the understanding of Japanese laws and regulations

Part 2
Key Administrative Measures of the Ministry of Health, Labour and Welfare
(Annual Health, Labour and Welfare Report 2007-2008)

* In Part 2 key administrative aspects of health, labour and welfare for FY 2007 are described along with those for up to June 2008.

Chapter 1
Promoting Measures to Secure Healthy Lives both Mentally and Physically, and Safe, High Quality, and Efficient Medical Care

Section 1. Enhancing a Safe, Reliable, and High Quality Medical Care System

1. Measures to Secure Emergency Doctors

In order to ensure public safety and trust in medical care, it will be important to secure an adequate supply of doctors in certain remote areas and in specific fields such as emergency child and obstetric medical services.

Accordingly, the Ministry of Health, Labour and Welfare, the Ministry of Internal Affairs and Communications, and the Ministry of Education, Culture, Sports, Science and Technology cooperatively compiled "Comprehensive Measures for Securing Doctors" in August 2005 and "New Comprehensive Measures for Securing Doctors" in April 2006. In addition, and as a result of discussions between the government and ruling parties on how to seriously cope with the growing number of appeals regarding a shortage of doctors throughout the country, the additional measure of "Regarding Emergency Measures for Securing Doctors" was compiled on May 31, 2007 for use in securing the necessary number of doctors that all the individual regions require.

(1) Establishment of a National Level Emergency/Temporary Dispatch System of Doctors to Shortage Areas

In response to "Regarding Emegency Measures for Securing Doctors",a system which doctors can be temporarily dispatched to emergency areas has been established. Doctors will be dispatched upon request from prefectures where appropriate regional medical care cannot be maintained even with the wholehearted efforts of the prefectural councils for securing medical services. Since being established, doctors have been dispatched twice to a total of 7 hospitals in 5 prefectures. The system has proved effective in enabling continued or resumed acceptance of child delivery and emergency patients.

In order to reduce the burden on medical institutions that are cooperating in dispatching doctors the FY 2008 budget will be used to cover the activities previously carried out by those doctors, thereby reducing the burden on other doctors. In addition, it will be used in measures that strengthen the medical service system such as in providing support for securing the system and maintaining medical devices.

(2) Creating a Hospital Work Environment for Doctors' Overtime

In recent years, doctors at hospitals, in particular those of a young or prime working age, face extremely severe conditions. To improve those conditions assistance services will be established in FY 2008 that support the introduction of a system that will include rotating shifts.

In addition, it was pointed out that doctors occasionally have to involve themselves in activities that could well be done by non-doctor personal, and that it is a contributing factor to the severe working conditions that hospital doctors face. Hence in December 2007 "Regarding the Promotion of Role Sharing Between Doctors/Medical Professionals and Office Workers" was issued and described typical activities that can be carried out by non-doctors in improving the work conditions of doctors through role sharing. In March 2008, it was ascertained that role sharing had been promulgated and put into practice by all. In addition, efforts are being made to disseminate and enlighten people on flexible work arrangements such as part-time regular employment.

Under a medical fee revision made in FY 2008 150 billion yen will be used in measures to improve the working conditions of hospital doctors that will include focused evaluations of obstetrics and pediatrics as well as the placement of medical clerks.

Furthermore, with consideration to reducing the workload of obstetricians, who currently face extremely severe work conditions, efforts are being made to establish a system in which midwives can be responsible for normal delivery cases through appropriate role sharing and cooperation between obstetricians and midwives. Support projects to establish hospital maternity clinics and midwife outpatient services at hospitals and clinics with obstetric services will be created in FY 2008. In addition, and as part of efforts to establish a safe and reliable child delivery system through disseminating and enlightening people on the use of midwives, a symposium on pioneer case studies at hospital maternity clinics and midwife outpatient services was held in March 2008.

(3) Creating Ideal Work Environments for Female Doctors

In order to prevent people from being underemployed due to child delivery or childcare and encourage them to return to work efforts are being made to promote ideal work environments for female doctors by providing facilities such as day care centers at hospitals. Additional measures include support hospitals that will provide training on returning to work and enhance the resource bank of female doctors by supporting their reemployment.

(4) Reviewing Quotas at Clinical Training Hospitals to Redress the Heavy Concentration of Interns in Urban Areas

A desirable clinical medical training system has been discussed by the Subcommittee of

Clinical Training under Medical Committee of the Medical Ethics Council since December 2006. In consideration of a written report that was compiled in December 2007 measures have been taken to enhance clinical training since April 2008, and include enabling flexible training programs and revision of the standards used in selecting clinical training hospitals. Furthermore, in order to redress the heavy concentration of hospital interns in urban areas, support measures for regional medical care training to be conducted in regions that have a shortage of doctors will be implemented starting in FY 2008.

(5) Establishment of a System to Help Prevent Medical Risk

1) The Japan Obstetric Compensation System for Cerebral Palsy

As part of measures to provide safe obstetric medical care, discussions were held on establishing The Japan Obstetric Compensation System for Cerebral Palsy. A preparatory committee operating The Japan Obstetric Compensation System for Cerebral Palsy, organized within the Japan Council for Quality Health Care, compiled a framework for the said system in January 2008.

One of the objectives of the system is to promptly compensate people for the economic burden of children that suffer from cerebral palsy as a result of medical accidents (including those due to both medical malpractice and non-medical malpractice) which occurred during birth to prevent and promptly settle disputes. An additional objective is to improve the quality of obstetric medical care by analyzing the causes of accidents and then provide that information for use in preventing similar accidents from occurring in the future.

Although the system utilizes private sector insurance, the Ministry of Health, Labour and Welfare will also give support for this system being introduced at childbirth institutions and help smooth operation of the system given this system will contribute to measures against the shortage of obstetricians and improve the quality of obstetric medical care through preventing repeated medical childbirth accidents from taking place.

2) Investigation of causes of death through medical accidents and recurrence prevention

In order to improve medical safety, it is necessary to establish a system for use in investigating the cause of death occurring from medical accidents (including those due to both medical malpractice and non-medical malpractice) and thus prevent their recurrence. In consideration of bereaved families wishing to first know the truth and then prevent any recurrences of a similar accident, it will be necessary to establish institutions that specialize in analysis and evaluation in securing medical safety.

The Ministry of Health, Labour and Welfare announced the Third Draft Proposal in April 2008

after listening to a variety of opinions. The "Draft Act for Establishing a Medical Safety Investigation Committee" was announced in June 2008 and is currently being discussed.

(6) Promotion of Training Regional Doctors or for Departments that Face a Shortage

In compliance with the "Comprehensive Measures for Securing New Doctors" made in 2006 and the "Regarding Emegency Measures for Securing Doctors" made in 2007, the number of doctors to be trained for regional placement or in departments specified by prefectures will be increased to 395 by FY 2009 through the use of scholarships. Starting in FY 2008 there will be an increase of 168 trainees at 16 universities.

2. Vision for Securing Safe and Expected Medical Care

In order to secure safe and expected medical care it is necessary to establish both a medium- and long-term medical care system vision and implement its reform with an eye to the future.

Accordingly, an advisory board of experts was organized within the Ministry of Health, Labour and Welfare. The advisory board has met a total of 10 times and compiled a "Vision for Securing Safe and Expected Medical Care" in June 2008.

The vision aims at fostering support for medical care by not only medical professionals but also by the public, including the patients and their families. The vision emphasizes the following three points: ① the number of medical professionals and their roles (increasing the number of doctors, improving their work conditions, and facilitating cooperation between the different professions and through team medical care), ② promotion of community support medical care (promotion of measures to support emergency medical care and "community-oriented medical care"), and ③ promotion of cooperation between medical professionals and patients and their families (the necessity for mutual understanding). Specific measures will be conducted for the realization of this vision.

3. Promotion of Medical Care that Respects Patients' Viewpoints and Establishment of a High Quality and Efficient Medical Care System

As a result of upgrade within the universal medical care insurance and free access system to allow people to receive the necessary medical care, the Japanese medical service system has become an important foundation for securing people's health. However, it does face the issue of reforms being promoted that will offer even higher-quality and more efficient medical services, to cope with changes in the medical care environment caused by further decreases in the number of children and the aging of society, advances being made in of medical technologies, and changes in the way people think.

In consideration to that "Draft Legislation to Amend the Medical Care Law for Establishing a Quality Medical Care System" was presented at a regular Diet session in February 2006 and approved on June 14, 2006. The law came into effect on April 1, 2007. A system in which public safety and trust in medical care can be achieved and high quality medical services adequately provided has been created through means such as reforming the medical care system and the following.

(1) Promotion of Information Made Available that Supports Patients and People being able to Make a Choice

In order to support patients and people to obtain sufficient information on medical care and thus make the appropriate choice the following efforts have been made:

① Increasing information being published in a system in which information on medical institutions is gathered and then made available to the people on a prefectural basis

② Increasing the number of departmental names that can be used in advertizing

(2) Securing a System to Provide Medical Services in All the Regions

1) Promotion of a division of roles and cooperation between medical institutions within the medical care plan system

The Medical Care Law was amended in 2006 and the medical care plan system revised to facilitate a division of roles and cooperation between medical institutions in providing seamless medical care in all the regions. In compliance with that revision new medical care plans in which the following content was incorporated have been formulated and announced by prefectures in April 2008.

① A concrete medical care cooperation system for four specific diseases and five services that include cerebral apoplexy, cancer, and emergency medical care

② A scheme in which easy to understand indicators and numerical targets can be clarified and post facto assessments then made

2) Emergency medical care

Securing emergency medical care systems for all the regions is important in ensuring that people can spend their daily lives without undue anxiety. In consideration of this the system has been systematically improved since FY 1977 based on sharing of roles in early stage emergencies, emergencies requiring hospitalization (second stage emergencies), and lifesaving emergencies (third stage emergencies). In addition, an emergency medical information system has been introduced that

supports more efficient emergency transportation.

Promotion projects to introduce medical helicopters have been implemented since FY 2001, and as of March 2008 have been operating in a total of 13 prefectures. In addition, aiming at securing a nationwide emergency medical care system through use of medical helicopters, the "Draft Law Concerning Special Measures for Securing Emergency Helicopter Medical Services" was presented at a regular Diet session in 2007 as a lawmaker-initiated bill and approved on June 19, 2007 (fully enforced on April 1, 2008).

Furthermore, in addition to providing child oriented emergency medical services as part of the general emergency medical services other projects have been promoted, namely emergency medical service support projects for children (since FY 1999) and model hospitals that provide child oriented emergency medical services (since FY 2002) in cases requiring hospitalization and establishment projects for early stage emergency medical service centers for children (since FY 2006). It has been pointed out that the need for out of hours medical services is increasing as a result of changes in the social situation and family environments caused by the declining birthrate, nuclearization of families, and increasing number of double income families. Projects put in place in response to that include child oriented emergency medical telephone services (#8000) and promoting awareness of emergency medical services for children that are available have also been implemented to support parents in deciding whether to immediately seek medical treatment or not and help alleviate any anxieties they may be facing.

With respect to the availability of emergency transportation a pregnant woman in Nara prefecture suffered a stillbirth during emergency transportation in August 2007. The Ministry of Health, Labour and Welfare in conjunction with the Ministry of Internal Affairs and Communications responded with an "Investigation of maternal and perinatal transportation in case of emergencies" for use in this particular case as well as in analyzing common problems across the nation. The investigation resulted in requests being made to prefectures in coordination with the Fire and Disaster Management Agency of the Ministry of Internal Affairs and Communications that ① full inspection of their emergency transportation system take place and that then in addition to developing measures by incorporating the results, ② the necessary measures be implemented such as establishing an emergency transportation support system, emergency medical services and maternal and perinatal services be coordinated, and pregnancy health examinations be promoted according to the actual situation in all the regions.

3) Medical care in disasters

Concerning measures for securing medical care in disasters such as earthquakes efforts are being made that include the establishment of core disaster hospitals and proving training for

Disaster Medical Assistance Teams (DMAT) in establishing a system in which expert teams can be sent to disaster areas to provide medical services.

Incorporating the experience brought about by the great Hanshin-Awaji earthquake that extensively damaged medical institutions prefectural efforts are being made to establish core disaster medical centers and local disaster medical centers which are capable of treating large numbers of patients in a serious condition. This will secure medical services along with medical support in disaster areas (disaster medical centers had been established at a total of 579 locations as of the end of FY 2007).

Training for DMAT members first commenced in March 2005 to develop their ability to promptly act during acute phase of disasters (first 48 hours after the attack). As of March 2008 442 teams had completed the training.

In addition, all medical institutions are required to ensure that their buildings and facilities are earthquake-proof and to make preparations for coping with an interrupted lifeline so that the safety of patients can be secured and it can function as a base for relief of the community in the case of a disaster occurring. The ministry's respective intention is to understand the disaster measures taken by medical institutions and based upon that understanding promote being prepared for disasters.

4) Medical care for remote areas and islands

It is difficult to secure medical services in remote areas and on islands because of the difficult transportation and regional conditions such as the low number residents. In consideration to this "health and medical care plans for remote areas" have been mapped out every five years since 1956. Efforts for improvements have been made according to the plans, and include support for clinics in remote areas, support for mobile clinics, securing transportation means for providing first aid, introduction of remote medical care, establishment of hospitals to support clinics in remote areas, and sending of locum tenentes to clinics in remote areas.

Since FY 2006, efforts to improve medical services in remote areas and on islands have been made through promoting the 10th medical care plans for remote areas (for the period of 2006 to 2010). In addition, as medical services in remote areas and on islands can offer the opportunity to acquire a wide range of clinical experience efforts will be made to facilitate young doctors' understanding that value as a measure to secure regional medical services.

(3) Securing Medical Safety

Securing medical safety is one of the most important medical care policy issues in Japan. Accordingly, the following measures have been promoted in complying with the "Comprehensive Measures for Promotion of Safety Measures for Medical Care" compiled in April 2002, the

"Emergency Appeal for Measures against Medical Accidents" announced by the Minister of Health, Labour and Welfare in December 2003, and the "Regarding Safety Measures for Medical Care in the Future" (report) in June 2005.

1) Systematization of medical safety support centers

In order to promptly cope with claims and consultations from patients regarding medical care medical safety support centers were established in total 47 prefectures. At present establishing those centers in their respective cities and wards with health centers and secondary medical areas is being promoted. As a comprehensive support project for counselors working at medical safety support centers and in order that they can respond appropriately to difficult consultations the Ministry of Health, Labour and Welfare has been conducting activities which include supporting training courses for acquiring specialized knowledge and improving their abilities and the collection, analysis and making available of information on the consulted matters.

In accordance with the medical care system reform of FY 2006 medical safety support centers have been legally established within an organization under the Medical Care Law and their functions expanded to secure medical safety through activities that include ① responding to claims and consultations from patients or their families regarding medical care and offering advice to the managers of medical institution, ② providing information to the aforementioned managers, patients, and families, and ③ providing training on medical safety for the managers and employees of medical institutions.

2) Obligations of medical institutions managers to secure medical safety

Managers of hospitals and clinics with beds are obliged to establish guidelines for safety management related to medical care and establish safety management systems that include providing training for employees. In the medical care system reform of FY 2006 the subject institutions were expanded to include clinics without beds and birth centers. In addition, measures such as establishing a system for the safe use and maintenance of pharmaceuticals and medical devices was also included in securing medical safety.

3) Medical accident report system

In order to prevent medical accidents and their recurrence it is necessary to collect a wide range of high quality information from medical practice sites, have it analyzed by experts, and the provide improvement measures back to the relevant sites. Since October 2004 the third party Japan Council for Quality Health Care (JCQHC) organization has been collecting information on medial accidents based on reports from the National Centers for Advanced and Specialized Medial Care, national

nursing homes for Hansen's disease patients, hospitals run by the National Hospital Organization (NHO), university hospitals (main hospitals) and special function hospitals. The collected information is analyzed with written reports being published every 3 months.

In the written reports particular accident cases are analyzed and examined in addition to being numerically analyzed. From the reported information the cases that require particular attention are then made available to all medical institutions through related organizations and prefectures.

(4) Securing and Improving the Quality of Human Resources to Support Medical Services

1) Clinical training system

Since April 2004 doctors engaged in medical examinations and treatments have been obliged to take clinical training, which had previously been voluntary, for 2 years after acquiring a doctor's license with the basic idea of offering doctors the opportunity to cultivate the appropriate bedside manner and acquire basic diagnosis and treatment abilities while recognizing the social role to be fulfilled by medicine and medical services regardless of their future specialty.

In addition, the Subcommittee of Clinical Training under the Medical Committee within the Medical Ethics Council commenced discussions on the desirable clinical training system in December 2006. The written report prepared in December 2007 was then taken into consideration in the criteria for designating clinical training hospitals.

2) Obligating reeducation of administratively punished doctors

Improving the quality of human resources and the skills of medical professionals such as doctors is an important issue in securing the quality and safety of medical care. Reeducation of administratively punished doctors is also important in securing the safety and security of patients as well as the trust of the in medical care.

In consideration of above since April 1 2007 punished doctors have been obliged to undergo reeducation in reconfirming their professional ethics and medical skills and to confirm if they are competent enough to resume medical practice. In FY 2007 reeducation took place for a total of 99 doctors and dentists.

In addition, any punished public health nurse, midwife, nurse, or assistant nurse has also been obliged to take similar reeducation training since April 1, 2008.

3) Clinical training system for dentists

The environment surrounding dental practices in Japan has undergone drastic change due to epidemiological transition and the diversification of people's needs related to the aging of society

and changes in the manner in which patients and dentists communicate in respecting the rights of patients. Dental skills are also increasingly becoming more advancing and specialized, and as a result all dentists need to fully understand and acquire the basic attitudes that are necessary in being a medical professional as well as the skills and knowledge that ensure safe, reliable, and high quality dental health care.

In consideration of that clinical training for dentists was made compulsory in April 2006, and obligated dentists engaged in dental examinations and treatments to undertake clinical training for a year or more after first acquiring a dentist's license.

With the new system dentists are trained not only at hospitals but also at dental clinics and hence clinical training featuring the advantage of including role sharing between university hospitals, hospital dentistry, dental clinics, and social welfare facilities can be taken as the first step in lifelong training.

The creation of the new clinical training system for dentists is expected to not only contribute to dentist training but also to being the cause of various changes that include changes in the dental care system itself and improved quality of dental services.

4) Improved quality of nursing human resources

The environment surrounding nursing in Japan has undergone drastic changes due to the rapid decrease in the number of children and the aging of society as well as through the advancement of medical technologies. The roles of nurses such as in supporting the safety and security of medical practice sites and in providing nursing care that is in accordance with patients' needs are expected to become increasingly important. And therefore improving the quality of nursing human resources is considered necessary. On the other hand, as nursing services have become more complex and diversified and public awareness on medical safety has been growing the scope of practical training as well as the opportunity for students to participate in training tend to be limited.

In consideration of that discussions have been held in the "Study Group on Upgrading Basic Nursing Education" since March 2006 with regard to the content of the education to be upgraded, improving the quality of the human resources of full-time instructors, and the methods used in practical laboratory training. In accordance with a written report prepared in April 2007 ministerial ordinances will be revised as needed in upgrading the content of the education and will include consolidation of practical training and new curriculums to be introduced in FY 2009.

In addition, the "Colloquium on Basic Nursing Education" has been held since January 2008 to discuss the quality of nursing human resources that will hereafter be required as well as the direction upgrading basic nursing education should take in training high quality nurses from a broad point of view. The necessary discussions in upgrading basic nursing education will continue to be

held.

(5) Social Medical Corporation System

In the medical care system reform of FY 2006 a social medical corporation system was established in order that private medical corporations can play a more important role in regional medical care. Social medical corporations are granted special courtesies such as tax breaks, can undertake specific profit-making activities, and are issued with social medical corporation bonds provided that the following requirements have been met: ① improved non-profitableness by limiting the ownership of residual assets in the event of dissolution, ② securing transparency in the management of medical practices by submitting annual statements of accounts including balance sheets to local prefecture offices and complying with provision for inspections, and ③ providing medical services in remote areas and emergency medical services for children as stipulated in the medical care plans.

(6) Promotion of Wood as the Building Material in Medical Institutions

Medical care is now required that takes into consideration the healing environment for patients. In consideration of this the effort to promote the mental relaxation of patients through active use of wood as the building material in medical institutions has taken place in recent years.

Accordingly, using wood as the building material will be promoted in such areas as the interiors for rehabilitation sectors, dining rooms for patients, and others.

4. Promoting the Dissemination of Generic Medicine

As the dissemination of generic medicine contributes to reducing the burden on patients and improves medical insurance finances, numerical targets were set to raise the share of generic medicine per unit to 30% or more by FY 2012 and will be aggressively promoted. The Ministry of Health, Labour and Welfare established the “Action Programs for Promoting Safe Use of Generic Medicine” in October 2007 and efforts have been made in accordance with this program to gain the trust of patients and medical professionals with regard to generic medicine. The efforts include securing a stable supply of generic medicine, ensuring its quality, and improving the dissemination of information on it. In addition, in the reform of the medical fee payment system of FY 2008, prescription forms were revised to include a check box to facilitate the use of generic medicine. The check box is marked if the prescribing doctor believes it would be harmful to change to a generic medicine. But if the box is not marked the originator products can be replaced by generic medicine at the pharmacy.

5. Promotion of Health Policy in Japan at National Centers for Advanced and Specialized Medical Care, etc.

Medical institutions operated by the national government and that fall under the jurisdiction of the Ministry of Health, Labour and Welfare currently consist of the National Centers for Advanced and Specialized Medical Care (hereinafter referred to as "National Centers") and the National Hansen's Disease Sanatoria. They strive to provide the consistent medical services that need to be available as part of national haelth policies in close cooperation with the National Hospital Organization (NHO). NHO was established in April 2004 after assuming responsibility for the national hospitals and sanatoria but excluding National Centers and the National Hansen's Disease Sanatoria.

National Centers consist of 6 main centers (National Cancer Center, National Cardiovascular Center, National center of Neurology and Psychiatry, International Medical Center of Japan, National center for Child Health and Development, and National Center for Geriatrics and Gerontology). By taking an advantage of the fact that patients with serious diseases and medical professionals that have specialized in those diseases are both available at National Centers the respective centers can offer advanced pioneering medical care, undertake research to develop breakthrough treatments, conduct training, and publish information.

With respect to division of and cooperation between medical functions, National Centers are expected to play an important role particularly in the raising the level of medical service for national health policies such as with cancer treatment.

As they are scheduled to become independent administrative agencies in FY 2010, National Centers are being required to establish their roles, functions, and systems. With regard to cooperating with regional core hospitals, National Centers are expected to act as a driving force in providing medical services, conducting research, developing human resources, and disseminating information as well as playing the role of developing advanced pioneering medical skills. It is also expected that National Centers will play a role in making policy recommendations. Furthermore, with respect to promoting innovations, National Centers are expected to act as the core institution particularly in fields that require focused promotion in establishing close cooperation with industry, universities, the National Hospital Organization and thus promote development of advanced pioneering medical technologies, pharmaceuticals, and medical devices.

The "Draft Act on Independent Administrative Agencies Researching Advanced and Specialized Medical Care" was presented at a regular Diet session in 2008 and concerns the necessary actions to make each of the 6 National Centers a non-public office type independent administrative agency in FY 2010. The draft act is currently still under examination. Upon establishment each of the National Centers will become research and development agencies (a

group of the leafing independent administrative agencies that carry out research and development) in accordance with the “Act on Improving Research and Development Capabilities and Promoting Research and Development Efficiently by Promoting the Reform of Research and Development System”, which was established at a regular Diet session in 2008.