ORIGINAL ARTICLE

JKMS

http://dx.doi.org/10.3346/jkms.2012.27.S.S82 • J Korean Med Sci 2012; 27: S82-87

Discussions and Implications of the Recent Enactment & Revision of the Healthcare Law

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Received: 10 June 2011
Accepted: 5 March 2012

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Recently, there have been many changes in the area of healthcare. There is no certainty how these changes will affect the healthcare system and public health. However, to at least have these changes positively implemented, it is clear that evaluation through continuous monitoring is necessary. The enforcement of the Medical Institution Accreditation and Medical Dispute Mediation Law as well as legal revisions regarding the public healthcare system are changes to improve the quality of healthcare, while at the same time, provide penalties for infractions of the new law such as medicine/medical device rebates; moreover, legal revisions regarding telemedicine are anticipated to impartially vitalize technical development as well as the pharmaceutical industry. For these changes to have a positive effect on the medical field and people's lives, an accurate comprehension of the system and understanding of the details is necessary to be able to respond sensitively to any changes in the future. Therefore, this paper examined the background information on the current discussion on the changes in the healthcare system, examined the detailed content of the system, and reviewed the areas that were in dispute as well as the main issues to contemplate the expected effects of the changes and future tasks that may be generated as a result. These considerations will act as foundation for an in depth understanding of recent trends in the healthcare system.

Key Words: Healthcare; Medical Dispute; Medical Institution Accreditation; Public Healthcare; Rebate; Telemedicine

INTRODUCTION

System, law, policy, and ethics play an important role in all aspects of human's life including health, and they usually work closely with each other building up a firm inter-relationship. This mutual operation macroscopically applies to the overall social order and at the same time, microscopically applies to the healthcare system.

Medical expenses compared to the GDP of Korea is quite low at 6.5% (2008) and is ranked 29th out of the 31 countries in the OECD while quality of health system is considered to be quite high within the OECD countries, and hence, Korean healthcare is recognized to be on a world-class level in cost-effectiveness for healthcare as well as in medical technology. Nevertheless, there are still various tasks left in the area of healthcare. Rapid increases in medical expenses and excessive medical treatments due to an aging society, advancements in medical technology, systematic problems where certain areas experience shortages in medical treatment supplies, rapid increases in health threatening factors such as smoking, alcohol, and TB as well as new types of contagious and environmental diseases, and insufficient industrial outcomes despite superior human resources are all still problems in healthcare today.

For active resolution of these problems, healthcare specialists spend much time and effort trying to create the most suitable plans for the betterment of the public health proposing various opinions for the desirable development of a public healthcare policy and reconciling ideas of stakeholders. These efforts result in policies or laws that apply to real life, becoming an opportunity to be an important step forward in the healthcare system. However, a close review and analysis process is necessary to decide whether the changes in policy induce a cleansing of the system.

Recently, various issues in the realm of healthcare have been legislated. How the institutionalization of these issues will affect healthcare should be observed from a long-term perspective. However, by examining the content and background of the changes, it could be an opportunity to anticipate the institutional inconsistencies or adverse effects that may arise in the future.

pISSN 1011-8934
eISSN 1598-6357

DISCUSSIONS ON THE ENACTMENT AND REVISION OF HEALTHCARE LAWS

Medical institution accreditation system

Background of revision

The medical institution evaluation system was first proposed by the Health Reform Committee in 1994 to enhance the quality of medical services and provide superior healthcare services to the public. Demonstrative evaluations were conducted on 227 hospitals for 7 yr starting from 1995, and the system was finally introduced into medical law from 2004. Since then, the evaluation system has succeeded in achieving significant results in improving service standards and inducing autonomous service quality enhancements at medical institutions. It has created patient-centered healthcare services and patients' rights protection, and promoted safety awareness.

However, several problems have been presented regarding the unrevised evaluation system. The credibility of the evaluation results cannot be guaranteed due to the absence of a specialized organization and professional labor force. In addition, medical institutions are encouraged to temporarily act in accordance with the evaluation schedule. Another problem is that the efficiency of the system is decreased by overlapping evaluations due to separate evaluations being done based on other laws (e.g. emergency medical institution accreditation) as well as evaluations based on foreign institutions (1).

In consideration of these problems, the 'introduction of the medical institution accreditation system' was selected as a national project after the inauguration of the new government in 2007. Various efforts including the operation of the Task Force and the convening of forums regarding system improvement have been achieved. In 2009, the Medical Institution Accreditation Promotion Team was organized, and a revised bill for medical law regarding the introduction of an accreditation system was passed in July 2010.

Main points of the revision

According to the revised medical law, article 58, the evaluation system was changed to an accreditation system, and accreditation was expanded to 2,679 medical institutions nationwide. According to the revised medical law, full-time professional workers from the accreditation institution have to evaluate whether the medical institutions satisfy the accreditation standards. With these evaluation results, medical institutions are classified as accredited, conditionally accredited, or non-accredited. If a medical institution was accredited, it means that the institution has fulfilled the satisfaction requirement for quality of medical service and patient safety. Then, the institution may utilize the evaluation results and accreditation rating in receiving administrative and financial support (e.g., designated to be a superior general or special hospital) from the government. Accreditation is valid for 4 yr and accredited medical institutions are granted benefits (e.g., incentives) in addition to the use of the accreditation mark. Furthermore, based on relevant regulations, medical accreditation institution can execute unified evaluations including integration of evaluations by other laws such as emergency medical institution evaluations and international medical institution evaluations.

Main issues and pros/cons

The 2010-revised bill of medical law was submitted to the National Assembly to introduce the accreditation system according to expanded social awareness on the intrinsic limitations of the medical institution evaluation system. Included among these are the bills proposed by Congressman Shim, Jae-chul on January 28, 2010 and Congressman Park, Eun-su on April 12, 2010. Although the two bills have the same purpose of introducing the accreditation system, they include different policy points regarding the range of medical institutions obligated to receive accreditation, governance installation problem that discusses the main policies related to medical institution accreditation, and the problem regarding whether the accreditation authority will be a special company or a non-profit foundation (2).

Furthermore, the conversion to a medical institution accreditation system is also criticized for providing a method for relieving medical institutions from the burden of compulsory evaluations. Compulsory evaluation is conducted heteronomously in order for medical institution to reach certain level of the quality of medical service and to resolve the gap between the level of the institution concerned and the standard level. Yet a new policy is with the object of aiming for the best quality of medical service upon voluntary motive, and for continuously developing towards the accreditation level.

Expected effects of the revision

With the conversion to a medical institution accreditation system, small and mid-sized hospitals, mental hospitals, and nursing hospitals, which were previously located in the blind spot of the unrevised evaluation system, have entered within the quality management system of medical service. In addition, the organization of the accreditation institution provided a foothold for constructing an accreditation system with international standards (3). Furthermore, the consumers' right to know and select are expected to be strengthened as compulsory announcement of accreditation results will provide information for the public (or consumer) during the selection of a medical institution.

Medical dispute mediation system

Background on the discussion for enactment

Medical accidents are a serious social problem. From the late 1980s, repetitive legislative attempts were made to achieve the enactment of 'medical dispute mediation law'. However, the

legislation continuously failed to achieve consensus regarding the main issues. With the postponement of the legislation, medical disputes in Korea were sporadically settled through various methods such as the court, the Korean Consumer Agency, the Korean Medical Association Society, societies for each medical specialty, private insurance, and self-settlement. The main problems as a result from such methods are the absence of objective databases regarding medical accidents and the failure to share information between institutions. Thus, a method for completely preventing the occurrence of medical accidents is yet to exist.

The establishment of an effective medical dispute settlement system that is sustainable in this rapidly changing healthcare environment is necessary in addition to the foundation of consistent policies and a system for preventing the occurrence of medical accidents. The shifting problem of the burden of proof, one of the biggest reasons that the legislation had foundered, could partially be resolved by the establishment of medical dispute settlement system that can perform as a professional authenticating role. The necessity for legislation is sufficiently emphasized by each system and active communication is should be carried out by the government and National Assembly. A bill related to medical accidents has been proposed in the 18th National Assembly in 2009. In April 2010, a final agreement was reached by the second subcommittee of the bill review system of the National Assembly Judiciary Committee. However, the bill is pending as it has yet been proposed in the plenary session of the Judiciary Committee.

Main points for alternatives

The medical dispute mediation bill currently pending in the National Assembly Judiciary Committee stipulates the establishment of an independent dispute settlement organization 'the Korea Medical Dispute Mediation Arbitration Committee (Arbitration Committee)' to investigate medical accidents conveyed from an authoritarian point of view and enable the arbitration committee to achieve consent judgment based on results. Furthermore, the settlement period of medical disputes is expected to be largely reduced through active use of alternative dispute resolution, such as adjustment, mediation, and reconciliation in order to minimize social costs according to medical disputes. There is a limitation on the legislation enacted in the aspect of taking willful transposition system of decision before litigation. However, it is differentiated from the existing steps in enhancing people's accessibility through developing a professional system equipped with mediation and authentication steps.

Main issues and pros/cons

There is no doubt regarding the necessity of the 'medical dispute mediation law'. However, there still are arguments for and against the main issues of the bill. In particular, civic groups and the medical world present different opinions regarding the exceptional clause for not implementing criminal penalties of healthcare providers in the case in which the victim does not desire punishment. Furthermore, civic groups are suggesting that the responsibility to prove the negligence of healthcare providers and the causal relationship between negligence and damage should be transferred to the healthcare providers.

Expected effects from the enactment of the law and future tasks

The Medical Dispute Mediation Law is prescribed in the Addendum to enter into force a year after promulgation so it will be implemented from April 7, 2012. In the implementation of this law, the most important task will be the stable establishment of the legislation while at the same time ensuring its effectiveness by designing a system that can guarantee fairness, speed, and professionalism in medical relief and mediation process. Therefore, the 'Arbitration Committee' that will be newly formed through this law must be operated as an independent institute that can guarantee third party impartiality. In this context, there needs to be preparation for procedures that can guarantee the objectiveness of members, which make up the 'Arbitration Committee', and since the mediation period is set to a maximum of 120 days, an objective research system and mediation procedures (manuals, guidelines, etc.) should be prepared to ensure an accurate and transparent mediation process. In addition, institutional strategies to attract active participation of professional personnel such as competent lawyers and doctors should be prepared to ensure the effectiveness of the system.

Discussions on legal revisions regarding the public healthcare system

Background on the discussion for the revision

The Public Healthcare Law was enacted in 2000 with the consideration that Korea's healthcare service had been focusing on public healthcare institutions. Its purpose was to stipulate an institutional framework that could supplement and keep in check the medical safety net of low-income earners and private healthcare institutions as well as for rational and effective public healthcare planning, adjustment, and evaluation.

Whereafter the proposition for the revised law regarding public healthcare was submitted to the National Assembly in November 2010 to be sent to the Health and Welfare Committee. The revised bill expands the public functions of healthcare system to include private medical institutions to improve and complement the public healthcare system. Vague functional differences exist between private medical institutions and public medical institutions that provide national medical services under the present national health insurance system (4). Nevertheless, public healthcare is defined as 'an activity executed by public healthcare institutions established by the government and local autonomous governments' according to the presently executed

http://dx.doi.org/10.3346/jkms.2012.27.S.S82

"Law on Public Healthcare". The effect of the policy is limited as it is only restricted to public medical institutions which only account for 6.1% of the total medical institutions in Korea.

Thus, the revised bill deviates from the perspective of possession and establishment of institution to re-define the concept of public healthcare from the functional perspective as the 'provision of necessary and beneficial medical service'. The main purpose of the revision is interpreted as the provision of legal evidence for helping private medical institutions to participate in the public medical industry.

Main points of the revision

The revised bill has re-defined the concept of public healthcare from a functional perspective and has newly established definitions for the public healthcare industry and institutions that execute public healthcare. These public healthcare institutions not only refer to public medical institutions of existing law, but also include private medical institutions that execute public healthcare.

Furthermore, the public healthcare general plan is established in connection with the regional healthcare plan in the Community Health Law and healthcare development plan in the Basic Law for the Health and Medical Field. This was done to establish and execute consistent and systematic policies on all levels, ranging from the central government to individual medical institutions. Connecting public healthcare general plan to healthcare ground plan and community health plan will enable policy enforcement to cover public health institutions and private health institutions. In addition, the revised bill designates and notifies regions with insufficient supply of medical resources and services as 'a medically vulnerable area', and provides evidence for arranging a healthcare labor force and provides expenses for the establishment and operation of medical institutions in vulnerable areas.

Main issues and pros/cons

The National Assembly has assessed the purpose of the revised bill, which is to achieve the efficient use of existing healthcare resources such as private medical institutions. Furthermore, the necessity of legal revision is acknowledged as the post-supplementation of legal evidence for medically vulnerable area projects and specialized medical center projects promoted by the Ministry of Health and Welfare in 2011.

However, a clear concept definition must be achieved regarding the function of public healthcare, which is the 'provision of necessary and beneficial medical services'. Furthermore, a method for attracting continuous participation of private medical institutions in public healthcare is required. Support for existing public medical institutions that had previously executed public functions must be combined to strengthen competitiveness. Thus, consideration of systematic consistency with different laws in a systematic approach to healthcare-related laws is required in addition to the intrinsic problems such as a point where there is no exact definition for 'medical publicity' in the law. The revised bill must not overlap or contradict regulations in laws related to the emergency healthcare law or the Law for Community Health.

Expected effects of the revision and future tasks

The definition of public healthcare and public healthcare institutions was vague so it was becoming an impediment to the development of a public healthcare system. The revised legislation redefined public healthcare focusing on the function to provide medical services that are essential and are in the public interest to the public rather than on the establishment or the ownership of public healthcare. At the same time, it applied a paradigm where the government could support and nurture as well as evaluate and supervise public healthcare functions by inducing an effective division of roles and by inducing the participation of public and private healthcare institutes. This is to investigate the new vision and role of public healthcare institutes and to anticipate creative development and performance of public functions as well as competitiveness and improvement in efficiency from public healthcare institutes. In addition, private healthcare institutes can participate in the public healthcare role to promote publicity and strengthen competitiveness, and this will contribute to the ultimate purpose of the law to improve the public health.

In detail, the direction of the existing public healthcare policy was completely amended to solve the problem where public healthcare was limited to 181 government and public hospitals owned by the country or local autonomous entities, excluding approximately 2500 private hospitals. This was effectively responding to important problems such as regionally vulnerable areas in healthcare. This also strengthened the public responsibility of private hospitals who received governmental support by participating in public healthcare. Institutes that are involved in public healthcare need to establish and evaluate plans for public healthcare through the participation of local residents, open accounting, and fulfill the necessary roles for the reduction of danger when there are expectations for major danger to the public health such as the H1N1 virus. With this revision of the law, the plan is to strengthen the publicity of the national healthcare system and greatly improve accessibility to compulsory healthcare services while heighten the synergy of the policy by systematically integrating existing projects of assigning public healthcare to rural areas and financing of healthcare institutes into the medically vulnerable area of policy.

However, to promote the active participation of private healthcare institutes, alternative plans and measures regarding healthcare such as adequate compensation for healthcare personnel through reform of the medical insurance system as well as a

stable supply of medical personnel through a long-term supply of medical school graduates, and a plan to heighten its effect. In detail, since Korea has private healthcare infrastructure in most regions, by clear establishment of the role of private and public healthcare and accompanying administrative and economic support such as medical fee support, no interest loans and public property from the government, and tax exemptions for private healthcare institutes that are fulfilling the role of public healthcare institutes to guarantee the effectiveness of the public healthcare policy.

MAIN DISCUSSION ON THE ENACTMENT/ REVISION OF LAWS RELATED TO HEALTHCARE INDUSTRIALIZATION

Dual punishment for medicine/medical device rebate

Background on the revision

Rebate dual punishment legislative bill was executed after passing the National Assembly in April 2010. The purpose of this bill is to newly establish regulations regarding sanctions for entities providing rebates in order to improve the transparency of medicine and medical supplies. Thus, giving and receiving of unreasonable economic profits in relationship with the adoption and prescription of medicine and medical equipment is prohibited.

Main content

All rebate provisions except for a minimum provision of samples, support of symposium clinical tests, product demonstrations, cost discounts according to payment conditions, and post-market surveys are prohibited. Doctors or pharmacists exposed to illegal rebates can be punished by the administrative measures of license suspension within 1 yr along with penal servitude for not more than 2 yr or a monetary penalty under 30,000,000 Korean won. Furthermore, pharmaceutical companies that have provide rebates can be punished by imprisonment for not more than 2 yr or by a fine not exceeding 30,000,000 Korean won.

Main issues and pros/cons

The rebate dual punishment system is criticized for its vagueness by the medical world and the pharmaceutical industry. There is an ambiguous criteria to define what is rebate practice regulated at the diversity of action manner because permissible range for rebate practices is restrictively listed and all other rebate practices is announced illegal. It is asserted that understanding of the penalty standards will be achieved only after the appearance of a case regarding direct sanctions through violation of the executed regulations.

Expected effects of the revision and future tasks

It is unreasonable to assume this issue related to the rebates from medicine and medical supplies is only a problem between doctors and the pharmaceutical companies. Social concern, that rebate practices pass off at compensation for the low medical fee, yet we should give a thought to a point that the cost is covered by the patients who pay for the medication, must accompany the issue to find a structural solution, and rebate practices for medicine and medical supplies must be improved upon to recover the ethicality and morality of healthcare providers (6).

Advanced nations such as the USA, Japan, and EU are already investing enormous expenses in R&D businesses to acquire competitiveness for the future bio-industry. In comparison, the pharmaceutical industry of Korea hardly possesses any competitiveness in the international market. Rebates of medicine and medical supplies particularly act as a factor that disrupts international development required in the pharmaceutical industry. The rebate problem must be solved to promote the continuous development of the healthcare industry including the pharmaceutical industry.

Revised bill: medical law related with telemedicine

Background discussion on the revision

Legal regulations related with telemedicine have been newly established through the revision of the medical law in March 2002. The telemedicine service industry was expected to grow as a result from the establishment of legal provisions. However, the currently executed medical law only permits teleconsultations that provide medical knowledge or technology between healthcare providers, and prohibits teleconsultations, prescriptions, and charges between healthcare providers and patients. This was done in consideration of the stability problem of medical services, the responsibility problem during the occurrence of medical accidents, and the leaking of private information during the approval of direct teleconsultations between healthcare providers and patients.

The medical law provision regarding telemedicine simply regulates the concept of telemedicine and does not provide solutions regarding general legal problems such as possibility of telemedicine between healthcare providers and patients, telemedicine range accessible in cutting edge u-health environment, etc., related to telemedicine (6). Thus, it raises the necessity of a medical law revision for solving issues related with telemedicine, such as approval of telemedicine types, clarification of responsibilities during occurrences of medical accidents, solution for info-communication technology error, payment method according to use of telemedicine, and the danger of leaking the private information of the patients.

Main points for alternatives

The revised bill for the medical law that was written for alleviating regulations on telemedicine in April 2010 was passed in the Cabinet Council to be submitted to the National Assembly. The purpose of the revised bill is to expand the use of the present

http://dx.doi.org/10.3346/jkms.2012.27.S.S82

regulations, which only permits teleconsultation between healthcare providers and to be executed between healthcare providers and patients. However, the revised bill is limited to patients with less approachability for medical services as it is restricted to re-consulting patients without medical risk. Furthermore, receiving prescription by proxy is permitted and patients can send electronic prescriptions to their pharmacy of choice during the execution of teleconsultation (7).

Main issues and pros/cons

Although telemedicine is regarded as a service industry field with great potential for growth, the medical world and civic organizations are loudly voicing concerns and opposition regarding approval of telemedicine between doctors and patients. The opposition of the medical world is because the introduction of the system can cause enormous negative effects on the health and lives of people since the medical safety of telemedicine between doctors and patients cannot be presently secured. Furthermore, the medical world states that the approval of doctor-patient telemedicine breaks down the existing healthcare delivery system and can cause the first collapse of healthcare based on regional approachability. Based on concern regarding the possibility of misdiagnosis of telemedicine and medical accidents, civic groups also emphasize the necessity of strict regulations and restrictions on patients that are permitted to receive telemedicine as well as on the facilities and equipment (8).

Expected effects of the revision and future tasks

The government has recently begun actively supporting the u-health service industry. These efforts are being done to foster an environment for providing telemedicine service and healthcare service in daily life through the fusion of medical service and IT technology to relieve patients from the burden of having to visit hospitals. The U-health service industry, including telemedicine service, possesses massive growth potential in Korea, a country equipped with top IT technical ability, an outstanding medical labor force, and a high receptive capacity for cutting-edge technology (9). Telemedicine service is expected to be further promoted by satisfying new healthcare paradigms, such as an aging population, increasing demand for high-quality medical services, and development of related technology.

CONCLUSION

Although there were many attempts to prescribe medical practice, the notion of medical practice could not be defined because of the complexity and diversity of the term. However, medical practice is not achieved by unilateral actions of the medical professional. The basic mechanism of medical practice is the interaction of the doctor and patient to accomplish the common goal of treating the disease. Therefore, the basis of healthcare policy or legislation is to search for ways to respect the rights of both the medical professional as well as the patient for this interaction to be more effective.

The recent amendments to the public healthcare system can be better understood when it is seen in this context, and appropriate measures to solve any complications or inconsistency that may arise can also be found. However, if inconsistencies or adverse effects can be anticipated and provisions made through active communication and evaluation, a more effective policy and system can be established that can contribute greatly to public health protection. In this sense, it is very important for medical professionals to sensitively respond to policies such as establishing mediation committees or strengthening medical safety nets so it is not partial to either the medical profession or patients for fair interaction to be achieved. This will be a valuable foundation for the development of the public healthcare system.

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