

CHAPTER SEVEN: Feedback from Regulators and Other Stakeholders

7.1 Presentation to the Healthcare Consultative Panel (HCP) of MPC

It was decided that the findings of the study be presented to the Healthcare Consultative Panel (HCP) of MPC to get the experts' feedback on the analyses and the proposed options on the regulation of private hospitals. The HCP is represented by key stakeholders and regulators – International Medical University (IMU - Chairman), KPJ Healthcare Berhad, Association of Private Hospitals of Malaysia (APHM), Malaysian Society for Quality in Health (MSQH), Ministry of Health Malaysia, United Nations University (UNU) International Institute for Global Health, Malaysian Medical Association (MMA), UKM Medical Centre, Malaysia Investment Development Authority (MIDA), Malaysia Healthcare Travel Council (MHTC), Malaysia Nursing Board, Ministry of Health (MOH), and Nilai University. Briefly, the function of the HCP is to advise and provide input to MPC on the development and productivity issues relating to the healthcare industry. It also encourages and advises on productivity initiatives carried out by MPC in the healthcare industry such as the benchmarking programme among private hospitals. As such this RURB study on private hospitals will be of interest to the panel. The following findings (Box 7.1) were presented to the HCP Meeting No. 2/2013 on the 1st November 2013 to inform the members on the issues and the proposed options and to get their feedback.

Box 7.1: Issues and Proposed Options in Private Hospital Regulation

Issue No. 1: Application Documentation

Application for operating licence renewal requires a lot of documentations, which contributes to huge burden in paperwork and administrative overheads to private hospitals. To compound this burden is the need to submit the licensing application at least six months before the current license expires (explicitly state in PHFS Regulations 138/2006). The proposed options are:

Option No 1: No change – continue with the existing practice

Option No 2: Using information technology

Option No 3: Moving from “evidence-based” to “information-based”

Issue No. 2: Complying with Licensing Requirements

The implementation of PHFS Regulations 138/2006, the licensing process integrates all other regulatory requirements from other regulations such as fire and building safety, machinery and equipment safety, environment, safety on drugs usage, information asymmetry, patient rights, public safety and the like. The outcome of integrating all these into a single licensing process invariably creates complexity and seriously burdens both the licensee and the regulator. The proposed options are:

Option No. 1: No change – let the change occur organically

Option No. 2: Review the Implementation of PHFS Regulations 138/2006 and Adopt Best International Practices

Option No. 3: Transparency through Continuing Education on Licensing Requirements

Issue No. 3: Dealing with licensing officers (on-site inspections, audits, or surveys)

There are variations on the assessment results. There are cases where an assessor citing requirements that are different from another assessor, or that the different level of strictness in the treatment of the requirements of the PHFS Regulations 138/2006. Such variations create confusions

on the licensee and at times created costly corrections being made. The governing regulation, PHFS Regulations 138/2006 is an extensively prescriptive. The proposed options are:

Option No. 1: Transparency through Continuing Education

Option No. 2: Transparent Standard Operating Procedure

Option No. 3: Establishing a Help-desk

Issue No. 4: Fragmented Processes

There are the DOSH, BOMBA, DOE, JPJ, Immigration, and the local authorities among some of the key players. The roles of all these players are explicitly or implicitly specified in the governing regulation. This fragmented processes leading to private hospital licensing create huge burdens to private hospitals. The proposed options are:

Option No. 1: No change or not direct action

Option No. 2: Redefining the regulatory oversight functions

Issue No. 5: Planning Approval for renovation, upgrade, extension, etc

The approval for any changes in existing facilities (renovation or upgrading) or expansion of facilities (extension or addition of new facilities) is taking too long to process and too many interactions are involved. It appears that there is not differentiating between minor and major changes renovation. The proposed options are:

Option No. 1: No change and continue with the existing practice

Option No. 2: Eliminate Planning Approval

Option No. 3: Adopt Risk-based Approach for Planning Approval

Issue No. 6: Occupational Licensing and Workforce Quality

With commercialisation of education, any students with the minimum qualifying grade but can afford out-of-pocket payment can enter for any professional education. Commercialization of health education is the imbalance between supply and demand. The drive for growth on higher education in healthcare has not match adequately the demand side of the equation, particularly for local graduates. The proposed options are:

Option No. 1: No change to current practice

Option No. 2: Monitoring Education Quality by the MOH

Option No. 3: A Formula for Supply-Demand Balance

Issue No. 7: Approval for Advertisement and Advertising Materials

Current requirements on approval of advertising materials are burdensome in terms of cost (the fee charge per approval at RM100.00), the interactions with the Medicine Advertisement Board, the MAB, (particularly for those hospitals located away from Klang Valley, the lead time (more than one week is deemed too long for hospital management planning) and the paperwork (need to send multiple hard copies for approval instead of on-line electronic media). The application has to be made to Putrajaya for any approval and submission has to be in hard copies. The proposed options are:

Option No. 1: No change to current practice

Option No. 2: Electronic means of submission and application

Option No. 3: Change the approval application to notification using ICT

Source: Author

7.2 Feedback from the HCP Members

Various HCP members gave their feedback on the findings presented to the panel. The Chairman maintained that patient safety and treatment outcome is most important in private healthcare services. He reiterated that it is also important that existing regulations are reviewed continuously to ensure that they meet with changing requirements of the healthcare industry.

Feedback from APHM Representative

- 1) The President of APHM gave his feedback on various issues. On the government initiative on the SL1M programme for unemployed graduate nurses, he reported that there private hospitals did not get good response from the group. Many have turned down the offer as they are already employed elsewhere with better wages than the training allowance.
- 2) APHM also raised the concern on the availability of houseman positions for new medical graduates. The output of medical graduates has exceeded the capacity of public hospitals to provide houseman positions. Unless the houseman training capacity is increased, the supply of new medical doctors will affect the demand.
- 3) On various approval certifications from other regulatory agencies such as DOSH, BOMBA, and others, the APHM stand that is that MOH oversight on these are necessary to ensure patient safety at the private hospitals. He reiterated that he observed that many public hospitals do not maintained these requirements because there is lack of such oversight.
- 4) On the issue of approval of advertisement materials, the panel was informed that in some countries patients' testimonials were being used. This is not allowed here.

Feedback from the MOH Representative

- 1) The MOH recognizes some of the issues raised and have been working on reducing these burdens to business. The regulator has been trying out the online submission for documentations and is in the process of ironing out the teething problems. At the moment, the online licensing renewal for private clinics has been successfully implemented.
- 2) On the submission of certified copies of APC, the regulator is already looking into the submission of personnel information rather than the certified evidences as required in the present practice.
- 3) On the inconsistencies in assessments by licensing officers, the MOH recognizes the problem, particularly with constant turnover of officers. The MOH has been making efforts to provide continuous training and supervision to new officers.

Comments from the HCP Chairman

The Chairman generally agrees with the feedback given by the members. He reiterated that the regulator should periodically review the regulations to keep up with the expectations of business and consumers.

7.3 Feedback from the Licensing Authority of the Ministry of Health (CKAP)

The focus of the meeting with officers from the licensing authority of the MOH represented by comprising Dr. Ahmad Razid Salleh, Director, Administration, Dr. Afidah Ali, Deputy director, CKAPS, and Dr. Alicia Liew Hsiao Hui, KPP, CKAPS (MOH), is to obtain clarification and understanding on the rationale and intent of the regulatory requirements and administrative processes involved in the regulation of private hospitals. A copy of the presentation made to the HCP was given to the regulator for reference. Specific questions of interest were then posed to the regulator and the recorded feedback is given in appendix 7.1. The analysis is reported below. *The author's views are given in italic.*

1) The Six-month Application Lead Time

From the regulator's perspective, the long lead time is to facilitate the private hospitals to meet the licensing requirements. The long lead time is to reduce the probability of delay in the issuance of the licence due to any compliance issues. Should the applicant experience any non-compliance issue, the lead time will be necessary for the applicants to make corrections non-compliance. However, the good intention of the regulator has created the sense of uncertainty and anxiety on the applicants.

A good tracking and monitoring system would help alleviate the uncertainty and anxiety for the applicants. An online system where the applicant can track (and monitor) the progress of their applications will help the applicant to manage their compliance issues. At the same time, such a system will ensure that the licensing officers are not subjected to undue interruptions to their work.

2) Online Computerize Application

The MOH has already implemented the online licence renewal application for private medical clinics. It is aiming to do the same for the case of private hospitals. However, the MOH is has poor initial trail of this application with the private hospital and is experiencing budget constraint to develop a more robust system. In the meantime it is trying to develop the system with internal resources (by the IT division of the MOH).

The view is that it is easier to develop the less complicated system for private clinics as the amount of application information to capture is small. The amount of information to capture for private hospitals will be a few hundred times more than that of a private medical clinic and as such the system will be very much more complicated. Also, the reliability of the Internet in various parts of the country is poor. Applicant will likely experience interruption in the data entry process when large amount of data need to be input.

3) On the necessary to capture large amount of data during the application

On the question - why the applicant needs to submit large amount of data in the application as the site audit or survey will be carried out during for the licensing? According to the MOH, certain data are required (specified in the regulation) that the MOH need to update its database and also this information form the basis for the issuance of licence. Another point is that the site audit assesses and evaluates other aspects of the hospital system that are not submitted in the application.

It is important that pertinent data are captured for the licensing process. Data capture can be reduced if only data on changes are captured. In other words, only data for updating the licensing requirements are captured. This would reduce the repeat submission of same data in the application process.

4) Difficulty with dealing with licensing officers

The issue of the difficulty of contacting the right person at the MOH for consultation on application issues is recognize by the MOH. As such, the MOH has schedule *special-client* day on every Friday of the week where applicants can meet with the regulators to sort out any issues they may have.

This is a good initiative by the MOH to be a facilitating regulator.

5) On continuing education of the private hospitals

The MOH currently does not have any allocation for such a programme. The limited personnel resources will not be able to cope with this. However, the MOH has carried out one-off briefings in the past to update the private hospitals on compliance issues.

The MOH could consider using external resources for such continuing education. It could engage business association such as APHM and MMA to support the continuing education programme for regulatory compliance.

6) On the approval for advertisement

We were informed that there has been proposal to amend the Medicines Advertising Regulation to put the responsibility of advertisement approval to CKAP. This will integrate the private hospital regulation to a single authority in the MOH.

This would be a good integration effort to have all approvals under one licensing authority as the requirements for advertising for private hospitals are different from medicine advertisement. However, there need to be some amendment to the existing PHFS Act 586 and the PHFS Regulations 138/2006.

7) On the planning approval for upgrade, renovation and extension

The team was informed that the approval process is much simpler than that of the planning approval required for the establishment of a new hospital. The planning approval is required as the upgrade, renovation or extension will require change in the licence details.

8) Annual Practicing Certificates

Although the occupational licensing of medical practitioners (physicians, nurses, midwives, medical assistants, dentists, pharmacists) are the purview of the various councils and boards and govern under their respective Acts, any issues relating to the licensing processes will affect the licensing of the private hospitals. The APCs are important to hospital licensing because they define the place of occupation of the professionals and the positions and responsibilities they hold with respect the hospital. Currently, the legal definition for Annual Practicing Certificates is on the year ending on the 31st day of December. This means that at the end of each year these councils and boards will be busy processing thousands of renewal applications. Thus there is the usually yearend jam for APCs renewal.

It does not appear that the various occupational regulators for medical professionals (MMC, MDC, MNB, MMB, MMAB and MPB) have the incentive to change the existing regulations.

9) Certified Copies of Annual Practicing Certificates (APC)

The rationale on the need to submit certified copies of APC in the licence renewal application was posed. The MOH realized the burden of having to prepare these documents, particularly for large hospitals which employ hundreds of medical professionals. The MOH informed that it is reviewing this requirement and proposing to change from this *evidence-based* input to a more efficient *information-based* input, where applicant will only have to submit the staff information, but certified *true and accurate* in the application. *This is also a recommended option from this study.*

7.4 Concluding Remarks

Firstly, the short 2-hour meeting has given valuable understanding on the regulatory and administrative rationale and intent of the regime. However, the time constraint did permit a more comprehensive review with the regulator. Continuing consultation will be made with the regulators at the next phase of the study – the Public Consultation phase.

The private healthcare business is highly regulated and this is important to ensure adequate oversight is made to protect the consumers in terms of patient safety, quality healthcare and patient rights. In business the focus on cost efficiency and revenue generation or profitability can be strong motivation to disregard these protections. As such, the regulator such as the MOH has the important oversight role to ensure that private healthcare providers behave in an acceptable manner.

To achieve patient safety certain specified minimum requirements with regards to the movement of patients must be met. This is to ensure that ambulatory patients can be move quickly and safely out of the hospital building during an emergency such as fire. Even within the building, patient must be able to be move quickly and along the safest and shortest route during a medical emergency. As such, location, layout and flow considerations become paramount to a good hospital system.

Quality health care can be achieved when all the key resources of people, materials, treatment and supporting facilities, utilities, the physical environment and standards for work processes are effectively organized and managed for systemic and integrated efficiency. A specialist medical centre, for example, must have the required resident specialists, it must have reliable treatment and supporting facilities, it must maintain the environment that will support adequate treatment and recovery, and other supporting staff and professionals. All these make the private hospital business a highly complex entity with high overheads and maintenance costs. There will always be the tension between maintain a high standard for healthcare and the need to control cost and generate revenue. The quest to generate revenue may motivate private healthcare business to provide unnecessary treatments to patients.

For private hospitals, the licensing renewal ensure that the MOH provide adequate oversights to protect the consumers and at the same time to maintain the country healthcare system to international standards. The current regulatory regimes and the regulators have proven their effectiveness in the oversight control. Nevertheless, the existing regulations need to be reviewed and the implementation processes and be improved to reduce and/or eliminate unnecessary regulatory burdens on private healthcare business.