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IMPACT OF THE PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998 (ACT 586) & REGULATIONS 2006 ON THE MEDICAL PRACTICE IN CORPORATE PRIVATE HOSPITALS IN MALAYSIA

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Abstract: This is a preliminary study which examines the impact of the "Private Healthcare Facilities and Services Act 1998 (Act 586) & Regulations 2006 (PHFA)" on the medical practice in the corporate private hospitals (for profit) in Malaysia since its implementation with effect from 1st May, 2006. This historical Act 586 regulates all private healthcare facilities and services for the first time in the country after 35 years replacing the Private Hospitals Act 1971. The rapid development of corporate private hospitals from the mid-1980s, which was in line with the "Malaysia Incorporated" concept had led to an unprecedented growth of corporate private hospitals, the repercussions of which, had wide social economic implications in the health care sector which resulted in inequitable medical and health resources, and in some resulted in poorer quality of care. It is not uncommon to hear negative media reports of unethical practice in the management of some of these private healthcare facilities: questionable hospitals' charges and padded bills; emergency services denied due to economic reasons, unreported assessable deaths, are some of the major concerns to policy makers. Further, it has been reported that professional medical indemnity and incident reports as a result of adverse events, medical errors and negligence in private hospitals are on the rise. Recognising the urgent need to address these issues of accessibility, equity, and quality care under a new regulatory framework, the Malaysian Government

stated explicitly the intention of the government that it would gradually reduce its role in the provision of health services and increase its regulatory and enforcement functions in the Seventh Malaysia Plan (1996-2000), the government's five-year development plans, and gazetted a comprehensive legislation, Private Healthcare Facilities and Services Act 1998 (Act 586) which was implemented in May, 2006. This study takes a close look at the regulation at work on ten study hospitals in the Klang Valley. The research methodology is designed by utilizing case studies and employs exploratory qualitative approach using key informant perception interviews and personal communications to obtain the relevant data. The research design encompasses two levels of studies, one at the corporate private hospitals sector as the regulatees and the other level at the Ministry of Health, Malaysia as the regulatory principal authority. Using the agency theoretical framework, study examines whether the regulatory the intervention have the desired effect on the behaviour of both the regulator and regulatees, and whether regulatory intervention achieve the Government's stated objectives of accessibility, equity and quality care. The empirical findings among others indicate that full compliance to the provisions of the Act 586 and its regulations remains a challenge in the corporate private hospitals. On the other hand, while the Act 586 provides the enforcement capacity, the Ministry of Health Malaysia, as the regulatory body

appears to be constrained with the insufficient human resources and information capacity. Faced with this challenge, the regulatory body seems to adopt a cautious and a non-controversial approach of "row less but steer more" in its role in driving the private health sector.

Keyword: Healthcare, private hospitals, regulations, Malaysia.

INTRODUCTION

ith the state's encouragement under its privatization policy in the 1980's, witnessed the rapid development and significant upsurge in the number of investor-owned corporate private hospitals providing curative services. These private hospitals were originally initiated by enterprising local doctors and subsequently with both local and foreign investors. With the significant increase in private investments and the unconstraint entrepreneurial initiatives, these fee for service hospitals started mushrooming throughout the country along side with other private health care facilities and services. This unprecedented phenomenon had far reaching consequences that lead to the major transformation in the health sector with the emergence of the current two-tiered public and private health sectors in the Malaysian health care system (Chee and Barraclough, 2007). In response, the Malaysian government came up with the Private Healthcare Facilities and Services Act 1998 (Act 586) together with its Regulations 2006, which is said to be the first comprehensive health care legislation regulating all private healthcare facilities and services in Malaysia.

This paper aims to look at the impact of the Private Healthcare Facilities and Services Act 1998 (Act 586) together with its Regulations 2006, in helping the government in its regulatory functions to ensure that private healthcare facilities and services provide good healthcare in terms of accessibility, equity, and quality care. The study in particular examines the conduct of the private hospitals in terms of compliance or non-compliance to the Private Healthcare Facilities and Services Act 1998 (Act 586) and its Regulations 2006.

The rest of the paper is organised as follows: Section 2 reviews past literature issues of accessibility, equity, and quality of private health care. Section 3 presents the methodology used and Section 4 describes the state of healthcare in Malaysia and the regulatory frame work. Section 5 presents the assessment on the impact of the Private Healthcare Facilities and Services Act 1998 (Act 586) together with its Regulations 2006, and its complexities. Lastly section 6 completes the article by presenting its conclusions.

LITERATURE REVIEW

Accessibility in healthcare

Notwithstanding the widely accepted notion of market failure, policy makers embarked on privatization agenda in health care, many of which resulted in undesired consequences which had prompted national policymakers' major concerns of accessibility, equity, and quality care (Evans,1997; Light,2000). While there have been extensive debates on the issue of accessibility to health care, little agreement has been reached on how to define it (Oliver and Mossialos, 2004).

From the World Health Organization's definition, accessibility to health services can be viewed from four dimensions which encompass the "availability, and acceptability" accessibility, affordability (WHO,2001a). The availability of services illustrates the relationship between the existing capacity and types of services provided and the type of demand and needs required. Accessibility on the other hand deals with individuals and the communities able to receive effective care (WHO, 2001b). Affordability is seen as the relative financial capacity of the individual's ability to meet the total financial needs, whereas acceptability addresses the issues pertaining to social, and gender acceptability among the population.

In spite of the numerous deliberations by healthcare proponents, it is not only difficult to define but also to measure health care accessibility. Chee and Wong (2007) argue that "even though morbidity indicators are used to reflect the health needs of the populations, it is difficult to ascertain whether the utilisation of services is adequate to meet morbidity levels. Utilisation rates are therefore used as indicators of demand rather than need or access." Further the encompasses concept of accessibility an understanding of health care needs, the availability of health facilities and services, and also the barriers to obtaining such health care.

Accessibility to health care may also be seen from a different perspective of the availability, affordability and acceptability of quality care. The availability of healthcare facilities and services is a crucial requirement to its accessibility. Affordability in turn reflects on the financial status of the individuals utilising the health care facility and services. However, this often involves an out of pocket payment or private payment for such services. While some services may be free, there is also an opportunity cost in terms of travelling cost to the healthcare facility and loss of income from the absence of work should also be taken into consideration. Acceptability of services refers to

whether the services rendered meet the expectations of the healthcare consumer. It "implies to the extent to which they are perceived as to be of good quality, convenient and amenable to use, effective in alleviating pain, or in preventing and treating disease, illness, and injury as well as being culturally appropriate"(ibid). Accessibility is said to be closely related to the concept of equity. While government regulatory intervention in health is often seen as the justification for equity, in reality these beneficiaries of the health care services provided are mainly to a selective rich segment of the population. Further, this rich-poor disparity is markedly evident for tertiary and secondary care compared to primary care.

Equity

The World Health Organisation (1981) considered equity as one of the basic prerequisites to the approach of primary health care. It implies fairness and justice (Durairaj, 2007). Hence, equity in health implies that there shall be fair opportunity for individuals to attain their full potential, and more realistically no one should be disadvantaged from achieving this potential. In the "Health for All Strategy Equity is defined as equal access to available care for equal need, equal utilization for equal need and equal quality of care for all" (WHO,1981). In health services provision, equity can be seen in two dimensions. It can be seen from the perspective of horizontal and vertical equity. The horizontal equity refers to equal treatment for equal need. While vertical equity implies that individuals with unequal needs should be treated unequally according to their differential needs (Zere et al. 2007).

Health equity has several standard definitions which suggest that access to health services should correspond with the need. Therefore the focus is to ensure that all people have access to a minimum standard of health services according to the need, not according to the ability to pay. Hence, equity in access to health services may be defined as equal access for equal need. In this respect, the disadvantaged communities may invariably experience multiple inequities and may not benefit the desired outcomes (Durairaj, 2007).

Quality in Health Care

Quality care can be understood in many different perspectives, although, there seems to be an understanding that there is no consensus on how to define quality of care. (Evans et al. 2001; Shaw and Kalo,2002; Sunol and Baneres 2003). The concept of quality of care may be seen and defined in the light of the provider's technical standards and patients' expectations. As Donabedian (1980) explained that "the quality of technical care consists of the application of medical science and technology in a way that maximises its benefits to health without correspondingly increasing its risks. The degree of quality is, therefore, the extent to which the care provided is expected to achieve the most favourable balance of risks and benefits." The concept of quality of care may also be seen and defined in the light of the provider's technical standards and patients' expectations. Nonetheless from the clinicians' perspective, the concept of quality in patient care is equated to the improved clinical outcome. This improvement meant lower mortality and better neurological function (Teasdale, 2008).

Patients, on the other hand, not only wish an optimum outcome but also, and increasingly, they regard the nature of the experience as important. "The quality of performance of the underlying systems, structures and processes that support the provision of care to individuals has clear relevance to organizations and communities" (ibid). In this respect, there are six main aspects or dimensions within the overall concept of quality (Lohr and Schroeder,1990). These encompass the aspects are patient's safety, effectiveness, patient centre, timeliness, efficiency and equity. These dimensions have become widely accepted and influential (Teasdale, 2008).

Asymmetric information and the principal-agent theory

Besides the issues of accessibility, equitability and quality of care, there is also the dilemma of asymmetry information which is particularly serious in the private health sector in spite of the advancement in this era of information technology. With the upsurge of commercialization and entrepreneurism in corporate private hospitals many patients as consumers of health care do not have the adequate knowledge to assess factors that are associated with quality care or to judge the appropriate quantity and quality of care. As such many of these patients are vulnerable and less informed consumers faced with a well-informed professional provider. Most of the time patients are unable to make informed decisions and unaware of their rights. In this respect the patients more often than not depend and delegate this decision making to the attending professional healthcare provider. This relationship exemplifies the principal-agent theory when one individual depends on the action of the other (Pratt and Zeckhauser, 1985). The main proposition of this theory is that the well informed agent wishes to maximises his own welfare and has divergent interests. Therefore there is a tendency towards conflicts of interests. Besides, these less informed patients may have difficulty in gauging the quality and the appropriateness of care they received

especially from the well informed private health care providers with high entrepreneurial initiatives (Culyer,1973; Bennett et al. 1997). Such problem of asymmetric information may be a barrier to accessibility, equitable and quality care. Further any decision not to purchase health care may sometime lead to irreversible disability or death and unlike other goods it precludes shopping around (Evans, 1984).

Hence it is not uncommon for the less informed patients to fear that they may lose their rights especially during hospitalization in a private hospital and even during consultation with a well informed doctor. Many patients are placed in a most vulnerable position especially during hospitalization. While there are various reasons for this misperception, however a major concern is the asymmetrical information gap between the patient and the doctors, and other healthcare professionals, or healthcare facility staff. Another major factor cited is the patients' lack of awareness of their rights (Lum, 2010). Patient's rights have been protected by professional ethics, and by health legislations (Silver,1997).

Under this study framework the MOH as a regulator is seen to be the principal while the corporate private hospitals are seen as the agents. Further the research also examines whether regulatory intervention had achieved the state's desired objectives of accessibility, equity and quality care in the private health care system. This study had sought the prior approval from the National Medical Research and Ethics Committee, Ministry of Health, Malaysia. Using the agency theoretical framework, the study examines whether the regulatory intervention have the desired effect on the behaviour of both the actors precisely the regulator and the regulatees.

METHODOLOGY

This study employs the exploratory qualitative approach designed by utilizing case studies, and using key informant perception interviews with semistructured questionnaires and personal communications to explore the impact of the new legislation and how these regulations work. Key informants are from the various relevant stakeholders in the healthcare sector divided into 3 categories of key informants: the private health sector, the public health sector, and the non-governmental organisations and patients.

Key informants from the public sector comprised of current and past officials from the Ministry of Health Malaysia (MOH) among others includes a former Director-General of Health, the Medical Practice Division, Planning and Development Division and Engineering Services Division and the Pharmacy Division, the State Medical and Health Department, medical consultants, medical officers, pharmacists, nurses and paramedic staff from public hospitals, and academicians from the universities. A total of 25 key informants were from this category.

While the key informants from the private health sector included past and present senior management of corporate private hospitals. Primary data were also collected from important key informants from the medical and dental professions such as the specialist consultants of various specialties and sub-specialties across the various corporate private hospitals under the study. Data were also collected from the private practitioners, the medical health insurance companies, managed care organisations, third party administrators and the pharmaceutical companies from the private healthcare sector. This category formed the largest group in the study with 69 informants.

Data from stakeholders' perception interviews were also gathered from past and current officials from non-governmental organisations such as the Malaysian Medical Association (MMA) which included two past Presidents, Federation of Private Practitioners Association, Malaysia Medical (FPMPAM), Association of Private Hospitals Malaysia (APHM) including a past President, Malaysian Society for Quality in Health (MSQH), Bar Council, Civil Society, and last but not the least the group of private patients and their relatives. While secondary data were obtained from patient bills, official press statements from MOH, official publications of public and private sources, internet, international healthcare conferences organised by the APHM, and healthcare seminars organised by the Faculty of Economics and Administration at the University of Malaya, Kuala Lumpur. Under this category 22 key informants provided their perceptions under the study.

For the purpose of triangulation, primary data were also obtained from a group discussion with the officials from a State Medical and Health Department in the Federal Territory of Kuala Lumpur. This exercise was to gain an insight of regulation at work and the enforcement capacity of the new legislation. A total of 116 key informants assisted in the study.

The research design encompasses two levels of studies, one at the corporate private hospitals sector as the regulatees and the other level at the Ministry of Health, Malaysia (MOH) as the regulatory authority. The study examines the effectiveness of regulatory enforcement of the Act 586 and its monitoring capacity in terms of its resources at the Ministry. Further to examine the effectiveness in terms of compliance of the new legislation, three categories of corporate private hospitals were identified in the Klang Valley.

Ten such facilities were chosen for this research study based on two criteria, first the utilised bed size capacity and the type of facilities and second the type of services provided. The first category comprises of 6 large sized corporate private hospitals with bed size capacity over 200 beds and providing full tertiary care facilities and services. The second category consists of 2 medium sized corporate private hospitals with bed size capacity between 100 to 200 beds and providing partial tertiary care facilities and services. The last category comprises of 2 small sized corporate private hospitals with less than 100 beds and providing secondary care facilities and services.

Healthcare in Malaysia: An Overview

Upon independence from the British colonialists in 1957, Malaysia had been a welfare-oriented state in terms of providing financing and provision of accessible public health care to all its citizens until the 1980s in line with the Alma Ata Declaration in 1970s (Roemer, 1991). Like many newly independent African and Asian countries, Malaysia was committed to the provision of universal access to primary health care in response to expectations raised before independence (Blooms et.al, 2008). Hence, health care policy was central and integral to the national development plans in Malaysia. During this period, health policy was of non controversial and without any political contention unlike policies on economy, culture and education (Chee and Barraclough, 2007). The state remained committed to the expansion of accessible network of rural health clinics providing free of charge primary health care services where the majority of the population was in the rural areas (Malaysia, 1986).

The extensive rural health development later formed the main infrastructure of the current integrated rural public primary health care system in the country. Besides inheriting a public hospital referral system from the British administration, new public hospitals were rapidly developed in the 1960s and heavily subsidised to cater for the local population in the urban areas. Adding plurality to the public health care sector, the existence of a few charitable and religious private hospitals were seen originally to provide care for the poor, however these institutions subsequently began catering for the affluent society to cross-subside the cost for treatment of the poor. Prior to the 1980s there were no corporate owned for profit private hospitals except for a few scattered number of small private maternity and nursing homes were also established with entrepreneurial initiatives

in the urbanised areas. The private primary health care was predominantly provided by the medical general practitioners for fee of service, together with the private dental practitioners and private pharmacists in the urban sector. Traditional medicine and complementary medicine were also seen to complement the private health care sector (Chee and Barraclough, 2007).

The public health care system has been described as egalitarian in character with its focus on primary care with accessibility assured in terms of geographical and financial perspectives. Malaysia's health care system had achieved remarkable advances in comparison with many developing countries especially Asian countries in spite of its low expenditure to the Gross Domestic Product (GDP). For instance, Malaysia spent about 2.9% GDP in the provision of health services in 1997 (World Bank,1999). The Malaysian health standard is said to be almost at par with those of developed countries (Meerman,1979).

Malaysia's health care system has also gained international recognition as one of the more successful systems among developing countries. Based on health indicators, life expectancy at birth has increased from 56 years in the 1950s to 71.70 years for male and 76.46 years for females in 2008, with a population of 27,728,700 people. The infant mortality as decreased significantly over the years from 84 per 1,000 live births in 1960 to 10.6 in 1996 and 6.3 per 1,000 live births in 2008. Further the maternal mortality rate of 0.3 per 1,000 live births was reported in 2008 (MOH,2008).

Health Care Privatization Policy

In line with the "Malaysia's Incorporated Concept providing a conducive environment in terms of infrastructure, deregulation, liberalization, and the overall macroeconomic management, the private sector is to assume the role as the main engine of growth" (Malaysia,1986; Jomo,1995). Strong encouragement is explicit in the economic policies in the form of granting tax incentives in the private health sector, among others such as industrial building allowance for setting up and commissioning hospital premises, exemption from service tax for expenses on medical devices and the use of medical equipment, and tax deduction for expenses on preemployment training (MOH,2002).

Consequently the number of private hospitals with entrepreneurial initiatives especially the investorowned fee for service corporate hospitals and other private facilities and services mushroomed

Table 1: Health Facilities (2008)

	NO.	BEDS
MoH Hospitals	130	33,004
Special Medical Institutions (MoH)	6	5,000
Non-MoH Government Hospitals	7	3,245
Private Hospitals	209	11,689
Private Maternity Homes	22	174
Private Nursing Homes	12	274
Private Hospice	3	28

Source: MOH, 2008.

tremendously throughout the country especially in the urban areas from the mid 1980s.

Statistically in 1980 for instance, there were 50 private healthcare facilities and services of which 10 were private hospitals. The total private healthcare facilities and services including private hospitals, maternity homes and nursing homes in Malaysia grew rapidly during the two decades from 50 in 1980 to 224 in 2001 in tandem with rapid rise is the surge in private investment and the national income. Subsequently, this rapid growth was mainly seen in the development of private hospitals which increased from 10 in 1980, to 32 in 1983, and 128 private hospitals in 2003 (Chee and Barraclough, 2007). Subsequently, as at 31st August, 2007 a total of 199 private hospitals were registered and licensed (MOH,2007).

Correspondingly, the private hospital beds increased significantly from 1,171 beds which formed 5.8% of the total hospital beds in the country in 1980 to 10,348 beds forming 28.4% of the total beds in 2001(Chee and Barraclough, 2007). Consequently in 2008 the total licensed 209 private hospitals had a total 11,689 registered beds in comparison with a total 130 MOH hospitals contributing 33,004 beds and another 6 other Special Medical Institutions under MOH adding 5,000 beds making a total of 38,004 hospital beds under the Ministry of Health, Malaysia as illustrated in Table 1. Further another 6 other non -MOH government had 3,245 beds. Besides, 22 registered private maternity homes had a total of 174 beds, 12 private nursing homes contributed 274 beds and 3 registered private hospices had 28 beds. The total private hospital beds accounted for about 22.08 % of the total 52,938 registered hospital beds nationwide (MOH,2008).

Issues in Malaysia's private healthcare

With the rapid growth of these private health facilities, issues of accessibility, inequity and quality care come to the fore in the Malaysian health care

system. Many of these private facilities and services were unlicensed and posed health threats and risks to the undiscerning public (Rosnah, 2007, 2002). Accessibility Issue

Since independence, the accessibility to public health care has been a primary concern to be addressed by the state. The government has improved the accessibility to public health care sector by increasing and redistributing the medical facilities and manpower resources. These resources included doctors and allied health professionals and even increase the availability of certain financed services (MOH, 2006a). However, this was not the case in the private healthcare sector. The rapid development of private hospitals with the unconstrained entrepreneurial initiatives and without an adequate prerequisite regulatory framework under the privatization policy over the decades had resulted in undesired consequences among others in terms of accessibility, equity and quality care. The availability of these private hospitals and other facilities are mainly in the high income urban areas which catered for affluent segment of the population. Further the charges spiraling exorbitant for private hospitalisation care formed a barrier to the large segment of the population in terms of accessibility and affordability. These major concerns culminated in the enactment of the new health care legislation under the Private Healthcare Facilities Act 1998 to address and achieve the national objectives of accessibility, equity and quality healthcare in the private sector (Sirajoon and Yadaz, 2008; Rosnah, 2007,2002; Malaysia ,2001).

Inequities in the distribution of health care services

While Malaysia recorded good health indicators among developing countries, Wee and Jomo (2007) argue that inequities exist in the distribution and utilization of health care facilities and services in terms of geographical location, states and social economic status. In their study of analyzing the public health expenditures and health care facilities, concluded that in spite of health care spending has increased over the years, priority accorded to health care has decreased relative to other sectors. Looking from the concept of equity, it encompasses both vertical and horizontal equity. Vertical equity is about unequal status amongst each person in the society. For instance in Malaysia, the richest 20 per cent of households earned 50 percent of the total household income, compared to 36 percent for the middle 40 per cent and 14 per cent for the poorest 40 percent in 1999 (Malaysia Plan, 2001). Therefore in the interest of vertical equity, if the poor cannot afford health care, the government has a moral and social obligation to provide subsidized health care services at the least.

From the context of horizontal equity, it concerned with the equal treatment of equals. In this instance the government is expected to treat each community equally irrespective of the geographical location or social economic status. The study shows that the physical distribution of government health services by stratum and the various states is inequitable. Therefore it affects the accessibility and utilization by lower income groups. In general, the priority accorded to health service has also declined over the years and more so to the lower income groups. Besides, the study did not have sufficient data to evaluate horizontal equity in government health spending (Wee and Jomo, 2007). Further total government development spending has been found to be inequitable (Wee,2006). Therefore the expectation of the regulatory intervention of the new healthcare legislation to address the major concern of inequity remains high (Sirajoon and Yadaz,2008; Rosnah,2007).

Quality healthcare

Abu Bakar (1995) reports that there is a dire need to promote accountability in quality healthcare. Equally significant are for those who need to know or have an interest in the shared information as asymmetric information in healthcare is still a serious problem. Besides, there have been negative reports over the mass media of variations in medical practice, quality care and concerns about the escalating and exorbitant healthcare cost.

While there are quality improvement initiatives in the MOH which employ various methods to measure and improve quality of service, in the private sector, there is still a dire need to emphasise the quality of health care service (Sirajoon and Yadaz, 2008; Abu Bakar,1995). The Government mandated that private health providers abide by the minimum criteria of quality improvement activities under the provisions of the new Act 586 and Regulations, and any contraventions would mean the possibility of the

license to operate a private hospital or facility and service to be terminated without assigning any reasons (MOH,2008).

Regulatory Framework: The Private Healthcare Facilities and Services Act 1998

In August, 1998 a historical legislation known as "Private Healthcare Facilities and Services Act 1998" which was gazetted and implemented with its Regulations in 2006 to improve accessibility to healthcare, correct the imbalances in standards and quality of care as well as rationalize medical charges in the private health sector to more affordable levels (Sirajoon and Yadaz, 2008; Malaysia, 2001; Rosnah, 2007, 2005, 2002). This new Act replaces the former Private Hospitals Act of 1971. The new legislation is the governing Act for all private health facilities and services in Malaysia. The mandatory information disclosure of private healthcare providers, the enforcement capacity, and the temporary order for the closure of facilities and services on non compliance now formed the major core provisions of the new private health care legislation (Sirajoon and Yadaz, 2008; Rosnah, 2002, 2005, 2007).

This study will examine some parts of the Private Healthcare Facilities and Services 1998 Act (Act 586) and Regulations 2006. It will mainly examine issues as follows:

Licensing of Hospitals

Licensing of private healthcare facilities and services is primarily to ensure that the minimum acceptable standards are complied with the provisions of the legislation together with the mandated accountability of private health care provider towards patient's safety, the upholding of patient's rights, and quality assurance (Kwegyir-Aggrey,1991; Bennett et al.,1994). The stringent provisions under the Act 586 amongst others stipulate the mandatory approval and licensing of all private hospitals together with other private healthcare facilities and services for the protection of patients and the accessibility of healthcare consumers in the country.

New Applications

With the implementation of the new Act 586 with effect from 1st May, 2006, all new applications for private hospitals and other private healthcare facilities and services now undergo a compulsory two-tier process of application. The first tier protocol is for the approval "to establish or maintain" mandated under Section 8 and 9 of Part III of the legislation while the second tier protocol is for licence "to provide and operate" a private hospital or other healthcare facility or service as stipulated under Section 15 of Part IV of the Act 586. Under the new legislation, application for a licence to provide and operate a private healthcare facility or service other

than a private medical clinic or private dental clinic shall be made within three years from the date of the issuance of the approval to establish or maintain in respect of such facility or service as provided for under Section 14 of the Act 586.

These new applications amongst others required the rigorous submission of the statutory details and declarations of the applicant, licensee, or holder of the certificate and person in charge, the detailed submission of the architectural building facility plans, justification of the need for a new facility or service at the proposed location, the human resource capacity plan with supporting evidence of qualified healthcare professionals valid annual practising certificates, financial investment capacity and the description of any high technology medical equipment intended to be used. It is only upon the MOH's mandatory approval to establish a private hospital that the construction and the setup of the facility commences based on the detailed submission of architectural building plan and other additional recommendations based on the provisions under the Act 586. Further it is after the completion of the new building facility that the application for licence to "provide and operate" of the private hospital or other healthcare facility or service is mandated. Under the second tier protocol as mandated under Section 16 of the new legislation, a pre-licensing inspection shall be conducted by a team headed by a medical practitioner from the MOH and the State Medical and Health Office at each of the proposed private hospital on the compliance and requirements under the Act 586 to ensure patient's safety and quality care (MOH, 2008).

Grant of or refusal to grant licence

Upon receiving and having considered the site inspection report under Section 16, and after giving due consideration, the Director General of Health shall have the discretion whether to grant a licence to operate a private hospital or private healthcare facility or service other than a private medical clinic or a private dental clinic, with or without any terms or conditions, and upon payment of a prescribed fees. Alternatively, he may refuse the application with or without assigning any reason for such refusal as stipulated under Section 19 of the new private healthcare legislation.

Adequate ventilation system

Under the Regulation 89, all rooms and areas in a private healthcare facility or service are mandated to be adequately ventilated. The ventilation system shall be adequate to provide one complete fresh air exchange every 6 minutes without recirculation in rooms or areas in which excessive heat, moisture, odour or contaminants originated. The regulation

stipulates explicitly all fresh air supply intakes shall be so located to ensure a source of fresh air away from any source of contaminants or odour.

However subject to the said Regulation 89, and under the stringent Regulation 198 further mandates explicitly that an operation theatre and its ancillary facility shall be mechanically ventilated to provide one hundred percent fresh air without recirculation. The operation theatres shall be provided with a minimum ventilation rate of twenty room volumes of air exchange per hour by mechanical supply and exhaust air system. The out-door air intakes shall be located as far as practicable not less than 7.6 meters from the exhausts from any ventilating system, combustion equipment, medical-surgical vacuum system or plumbing vent or areas which may collect noxious fumes. The bottom of out-door air intake shall be located as high as practical but not less than 0.9 meter above ground level or if installed through the roof is 0.9 meter above roof level. Further all ventilation or air conditioning systems serving the operation theatres shall have a minimum of three filter beds of High Efficiency Particule Air Filter (HEPA). These are some of the major requirements pertaining to the air ventilation system in the operation theatres and other sensitive areas to be complied by private hospitals and one of the most challenging in terms of compliance.

Penalty for unlicensed private healthcare facility

With the implementation of the new legislation, any person operating an unlicensed and unregistered private healthcare facility or service contravenes Section 3 or Section 4 of the Act 586 commits an offence and shall be liable, on conviction to a fine not exceeding three hundred thousand ringgit or to an imprisonment for a term not exceeding six years or to both in the case of an individual person. For a continuing offence, to a fine not exceeding one thousand ringgit for every day or part of a day during which the offence continues after conviction. In the case of a body corporate, partnership or society committing an offence and upon conviction shall be liable to a fine of not exceeding five hundred thousand ringgit and for a continuing offence, to a fine not exceeding five thousand ringgit for every day or part of a day during which the offence continues after conviction. This penalty of hefty fine and imprisonment upon conviction serves as a serious deterrence to private healthcare providers of operating unlicensed facilities where patient safety may be compromised. This sanction is a departure of the meagre penalty of one thousand ringgit fine imposed for operating an unlicensed private facilities under the old legislation the Private Hospitals Act 1971 and its regulations.

Suspension and revocation of approval and licence

Further, the provisions under Section 43 to Section 51 of the Act 586 provide an unprecedented immense statutory power to the Director General of Health who may refuse to issue or renew a licence if he is not satisfied as to the character and fitness of the applicant be it a natural person, a body corporate, partnership or society without providing any reason. Besides, he is empowered the refusal if in his opinion the premises in respect of which the application is made are unsafe, unclean or unsanitary, or inadequately equipped and the staff is inadequate or incompetent for the purpose of the private healthcare facility or service. Under Section 52 to Section 53 of the Act, the Director General of Health is vested with vast statutory power on the temporary closure of any private health care facility or service if it appears to him that the continued operation of such facility and service would pose a grave danger to the public in terms of patient safety.

This unprecedented enforcement capacity of regulatory sanction for the temporary closure of any private health care facility or service for noncompliance under the new Act 586 is a departure of the old healthcare legislation. The Private Hospitals Act 1971 did not have the provisions for enforcement capacity even to the extent of entering and inspecting any private hospital premises. Therefore the new enforcement statutory power under Part XVI of the new legislation serve to overcome the gap of perennial inadequacy of enforcement and also serve as a serious deterrence to private healthcare providers to ensure public accessibility towards patient safety and quality care.

The failure to comply to this order of temporarily facility closure under the Act 586, commits an offence and if found guilty shall be liable to a hefty fine not exceeding fifty thousand ringgit or to an imprisonment of a term not more than a year or both for sole proprietor. In the case of continuing offence, the penalty is to a fine of one thousand ringgit for every day during which the offence continues after conviction. For a body corporate, partnership or society, to a fine of not exceeding one hundred thousand ringgit and an imprisonment to a term of not exceeding one year or both.

Accountability & Responsibility

Under Part VI of the Act 586 which encompasses Section 31 to Section 38 explicitly stipulates the accountability and responsibilities of a licensee, holder of certificate of registration and the Person in charge (PIC). This accountability not only demands high answerability but also having the legal obligation to sanctions of the legislation (Schedler, 1999; Mulgan, 2000; Travis et al., 2002). In this context, the licensee under the Act is highly accountable to ensure that the health care facility or service such as the private hospital is maintained or operated by a person in charge who shall be a registered medical practitioner under the law and hold such qualification, have undergone such training and possess such experience as may be prescribed under Section 32 of the Act 586. This is to ensure the patient's safety and accessibility to facility and services with quality care.

This section of the Act 586 also stipulates a person in charge shall carry out such duties and responsibilities as may be prescribed by further regulations. Even for any change of person in charge, it shall be a duty of the licensee to notify the Director General within fourteen days of its occurrence of change together with documentation of registration relating to the qualifications, training and the experience of the new person in charge.

The failure to comply under the said sub section (1), commits an offence. In furtherance, the licensee shall be accountable to inspect the licensed or registered private healthcare facilities or service in such manner and at such frequency as may be prescribed to ensure patient's safety. Besides, the licensee is also accountable that persons employed or engaged by the licensed facility or service are registered under any law regulating their registration, or in the absence of any such law, hold such qualification and experience as are recognised by the Director General of Health.

Further, Part III of the Regulations 2006 encompassing Regulation 11 to Regulation 20 mandates the planning of the organisation and management of the private hospitals and other private healthcare facilities or services. Under Regulation 11 stipulates that all private healthcare facilities and services shall have a plan of organisation outlining the staff and practitioners in the facility and the chain of command. Further as provided under Regulation 13 the PIC is responsible on the employment of qualified healthcare professionals including foreigners registered under the law and recognised by the Director General of Health. Besides, the licensee or PIC of a licensed private healthcare facility or service shall not indulged in any form corrupt practice of fee-splitting and shall ensure that all healthcare professionals do not practise fee spitting too. Any person who contravenes these subregulations commits an offence and shall be liable on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or both.

FINDINGS & ANALYSIS OF REGULATORY INTERVENTION

Mandatory approval to establish and licence to operate a private facility

With the implementation of the new legislation effective from 1st May, 2006, all existing private hospitals and other private healthcare facilities and services which had been licensed under the previous Private Hospitals Act 1971 were deemed to be licensed facilities and services even though they do not have the full compliance. From the study, eight corporate private hospitals namely A, C, D, E, F, H, I, and J were licensed under the old legislation Private Hospitals Act 1971 and two other corporate private hospitals namely B and G were licensed under the new private healthcare legislation Act 586.

Six of these study corporate private hospitals A, B, C, D, E and F are classified as big hospitals with bed size capacity over 200 and providing tertiary care facilities with various specialty and subspecialty services. These corporate private hospitals are well equipped with the latest state of the art medical technology and sophisticated modalities. While the another two study corporate private hospitals G and H are been classified as medium size with bed capacity between 100 to 200 beds offering partial tertiary care facilities with specialty and a few subspecialty services. Finally the remaining two corporate private hospitals I and J are been classified as small size hospitals providing secondary care facilities and a few "bread and butter" specialty services such as internal medicine, general surgery, obstetrics and gynaecology and paediatric medicine. In terms of corporate ownerships, six of these private hospitals namely B, C, D, E, F and I are considered as government linked corporations (GLCs) which the state has majority vested equity interests while the rest of the private hospitals namely, A, G, H, and J though are non government linked corporations which are stand alone corporations but somehow have some GLCs or at least a 30% mandated bumiputra equity participation as illustrated in Table 2.

According to key informants and through personal communications at MOH, many of these corporate private hospitals and other private facilities were given the grace period to comply with the minimum standards under the new regulations as soon as possible for further improvements before the next license renewal. Many of these big corporate private hospitals took this opportunity to embark on the various refurbishment works and building expansion developments of various degrees as part of the business expansion programmes such as Hospital A, Hospital C, Hospital D, Hospital E and Hospital F. However in reality, the main objective is to a larger extent to comply with the new stringent regulations among others especially on the additional special requirements imposed such as on the air ventilation system in the critical areas and the additional requirements for emergency care services.

This immediate impact of compliance has invariably incurred various degrees of unprecedented additional operational and development costs to corporate private hospitals. Of these study corporate private hospitals, seven of these facilities were commissioned with purpose-built hospital premises and the other three facilities were however operating on converted commercial shop lots premises or non purpose-built hospital premises which had been licensed under the previous legislation. These non purpose built hospital premises had been reconfigured and renovated extensively to serve the purpose as a private hospital based on the basic provisions of the previous old private health care legislation. However with the implementation of the new legislation, most of these hospitals now faced a new challenge in terms of compliance for patient safety and quality care. Old purpose built hospital premises built over the decades have also faced similar dilemma. Realizing their shortcomings and the impact of the Act 586, the management of some these corporate private hospitals have even shifted their operations to new purpose built premises in terms of compliance. For instance Hospital D has now moved into a new adjacent purpose-built hospital premises within its hospital complex. On the other hand other corporate private hospitals such as Hospital H, I and J, which are extremely cost conscious had preferred to adopt a cautious "wait and see" attitude to assess the impact of the enforcement capacity especially those non purpose-built corporate private hospitals on commercial premises which had been licensed under the previous legislation. Patient's safety measures had invariably been compromised especially on the additional special requirements imposed such as on the air ventilation system in the critical areas and the additional requirements for emergency care services. Subsequently these corporate private hospitals such as H, I and J managed to do some cosmetic refurbishment works hoping to satisfy the minimum acceptable standards of compliance for patient's safety according to some insiders sources.

Hospital	Bed Capacity	Type of Facilities & Services	Type of Premises	Type of Corporate Ownership	Legislation under which they were licensed
А	> 200	Tertiary Care	Purpose Built	Stand Alone Corporation	Hospitals Act 1971
В	> 200	Tertiary Care	Purpose Built	*G.L.C.	Private Healthcare Facilities & Services Act 1998
С	> 200	Tertiary Care	Purpose Built	*G.L.C.	Hospitals Act 1971
D	> 200	Tertiary Care	Purpose Built	*G.L.C.	Hospitals Act 1971
Е	> 200	Tertiary Care	Non Purpose Built	*G.L.C.	Hospitals Act 1971
F	> 200	Tertiary Care	Purpose Built	*G.L.C.	Hospitals Act 1971
G	> 100- 200	Partial Tertiary Care	Purpose Built	Stand Alone Corporation	Private Healthcare Facilities & Services Act 1998
Н	> 100- 200	Partial Tertiary Care	Purpose Built	Stand Alone Corporation	Hospitals Act 1971
Ι	< 100	Secondary Care	Non Purpose Built	*G.L.C.	Hospital Act 1971
J	< 100	Secondary Care	Non Purpose Built	Stand Alone Corporation	Hospital Act 1971
*Government Linked Companies					

Table 2: Licensing of Hospitals

Total private hospitals licensed

After a year into its implementation, in 2007 witnessed the desired effect of the Act 586 with the registration of a total of 199 licensed private hospitals nationwide (MOH,2008). The majority of these licensed private hospitals numbering at least 190 are corporate for profit private hospitals. Besides these private hospitals, other facilities that were licensed were 21 private maternity homes, 10 private nursing homes, 2 private hospices, and 2 private ambulatory care centre. But in the case of private haemodialysis centres, it was reported that the MOH faced huge challenges as this was the first time private haemodialysis centres have been regulated. Out of a total of 174 private haemodialysis centres which had been granted approval to establish or maintain services, only 6 have been granted a license to operate or provide the service (ibid). However, as the study is on private hospitals, other private health facilities will not be dealt with in detail.

The Klang Valley consisting of the developed and high income states of Federal Territory of Kuala Lumpur and Selangor have a total of 22 new approved applications forming 47.83% of the total new application approvals for hospital establishments. Besides, there were 38 other approved applications from the developed west coast states of Peninsular Malaysia which accounted for 82.6% of the total approved applications for private hospital establishments nationwide (ibid).

However the less developed east coast states of Pahang and Teregganu with 4 approved applications forming only 8.7% of the total approved applications. Whereas the much less developed states of Sabah and Sarawak in east Malaysia accounting for a similar 8.7 % of the total approved applications. These statistics indicate that the gross inequitable geographical distribution for the new approved applications for private hospital establishment which would further exacerbate the problem of disparity and inequitable distribution of private hospitals. The desired effect of the regulatory intervention for an equitable geographically distribution or zoning of private hospitals remained an insurmountable challenge.

Compliance: Adequate ventilation system

The regulatory intervention has to a certain extent influenced the behaviors of the private healthcare providers in terms of compliance of facility building structures for patient's safety. This is evident in one of these study corporate private hospitals. Hospital C, a renowned GLC entity undertook an unprecedented major renovation and refurbishment works especially on the installation of the 100% fresh air ventilation system which cost the management a hefty RM 2.0 million expenditure. This justification for the major work was because the hospital's old ventilation system compromised of a mixture of fresh and recirculation air which did not comply with the stringent provisions under the new regulations (personal communications). This complex renovation work had to be carried out under close supervision and scheduled progressive phases in order not to disrupt the business operation of the hospital services and more importantly not to cause inconvenience to patients. The compliance work covering the various sensitive areas such as the operation theatres, labor delivery rooms, and critical areas of intensive care units in the hospital had extended over a period of one year according to key informants.

Accountability & Responsibility

The study reveals that in all the study hospitals, the role of a person-in-charge has been entrusted with a registered medical practitioner designated as a medical director who is normally an employee of the corporate private hospital which is headed by either a Chief Executive Officer or a General Manager who may or may not be a registered medical practitioner. There are also exceptions where specialist consultant has been appointed as a medical director with financial incentives. This creates the holder of the medical director post the most challenging balancing act of remaining as a clinician on one hand and on the other hand being part of the management of the corporate private hospital.

Notwithstanding the high accountability and responsibility sanctioned under the Act 586, in reality it is a challenge for the person-in-charge of the corporate private hospital to make major independent decision-making which may be in conflict with the current corporate policies and business decisions. Unless the person-in-charge commands a respectable major share equity either through direct or indirect share holdings in the corporation, decision making is a challenge. Therefore the high accountability mandated under the legislation for the appointment of person-in-charge is no more seen as attractive and glamorous position for any senior practising consultant specialists vying for this role in a private hospital unless highly compensated. The management of a corporate private hospital may find alternative to employ on contract basis a retired registered medical practitioner who doesn't mind marking his time or a newbie to save cost.

In the study corporate private hospital I, a senior practising consultant had relinquished his role as the

person-in-charge with the implementation of the Act 586 and instead focussed on his clinical medical practice. As accountability has a high degree of complexity and knowing that shortcomings in terms of compliance in corporate private hospital were beyond his control, it was in the best interest for him to remain as a clinician.

Circumvention of the Act 586: To circumvent the provisions under the Act 586 in terms of compliance, the management of Hospital I for instance offered this complex role to a young enthusiastic registered medical officer Dr J, who was then employed at the Emergency Department of the hospital. With an additional financial incentive of RM 2,000.00 allowance per month, the medical officer agreed to accept this important position even though he was not even considered to be upgraded and designated as a medical director. As cost containment measure is an important consideration in the management of corporate private hospital and human resource staffing cost forming a significant portion of the overall operating expenditure, the recruitment of adequate staffing often come under close scrutiny and shortage of qualified staff is common and remained a challenge in terms of compliance. In this respect quality care may sometimes be compromised according to key informants.

The person-in-charge in this case is not only being a junior employee in the private hospital in reality, has no authority to address any outstanding oversights and shortcomings. The perennial problem of shortage of medical officers in the Emergency Department using part-time locums had resulted the person-incharge to be charged with neglecting and disregarding his professional responsibilities by employing and permitting an unregistered person, one Dr. K, an unregistered practitioner, to practise medicine at the private hospital. The locum doctor was found treating patients, administering and prescribing medication, without ensuring that such a person has obtained a valid Annual Practicing Certificate to practice medicine at the said private hospital under the Code of Professional Conduct.

The PIC was subsequently found guilty of infamous conduct in a professional respect under Section 29(2)(b) of the Medical Act 1971 on the grounds that as the person- in-charge of the hospital, he is accountable for the management and control of all professional matters in that facility, which includes employment of doctors including locum doctors. According to a key informant, the person-in-charge was initially recommended to be charged under the provision of the new Act 586 instead of the Medical Act 1971.

Concerns on the Implementation of the Act 586 & Regulations 2006

The implementation of the new legislation was not uneventful. MOH faced huge challenges in the registration and licensing of private healthcare facilities and services especially the private clinics resulting in nationwide protests and severe criticisms from the private medical and dental practitioners over the stringent provisions regulating their practices especially in the clinics. While the professional bodies of Malaysian Medical Association (MMA) and Malaysian Dental Association (MDA) welcome the implementation of the new legislation to regulate private healthcare facilities and services in the country, especially to prevent the setting up of such facilities by untrained and unqualified persons, and the provision of services which may be below the accepted standards of medical care, the Act 586, however, is seen to be "draconian" and "criminalisation" (MMA&MDA, 2006).

Memorandum to Health Minister - "Draconian Act": One of the major concerns particularly is the serious implication in the Act 586 and Regulations 2006. The fear is the possibility that medical and dental practitioners while providing a genuine professional service to their patients may on the slightest failure to comply with the stringent provisions stipulated under the new legislation, be fined heavily, imprisoned or both. Consequently, this implication may lead to defensive medical practice in the country. Besides, there is also a possibility of the reluctance and fear on the part of practitioners to commence private practice. Eventually, these may in the end be counterproductive and negate the primary objectives and spirit of the new healthcare legislation. Subsequently both professional bodies submitted a joint memorandum to the Minister dated 13th July, 2006 to review the regulations affecting them and called for the deferment of implementation (MMA&MDA, 2006).

Suspension and revocation of approval of licence: On the provision to grant of or refusal to grant licence under the new Act 586, the MMA and MDA raised concern as it seemed irregular that a license can be refused without any reason. In a Joint Memorandum to the Honourable Health Minister dated 13th July. 2006. MMA and MDA argued that grounds for refusal should be revealed. The Site Inspection Report under Section 16 of the Act 586 particularly on the adverse comments, or shortcomings, should be revealed to applicant. An appeal mechanism should be instituted within this section without having to appeal to the Honourable Minister as provided for under Section 101 in Part XVII of the Act. It recommended a resubmission of application for re-inspection after remedy of shortcomings should be allowed Besides, the professional bodies argued that the prescribed fees for registration and renewal of licence for facility and service are exorbitant (MMA/MDA Memorandum, 2006). Notwithstanding, according to key informants as long as the compliance and specifications are met under the Act 586 and its Regulations 2006, an approval shall be considered and granted.

Political "invisible hands": While the Act 586 provides the immense statutory power to the Director General of Health, in reality the intervention of "political invisible hands" may pose huge challenge and constraint for the Director General of Health to exercise the full power vested in him. Exercising the immense statutory power in good faith is a challenging and daunting task. For instance a case of a prominent clinician owned highly commercialised private healthcare facility which is known for its dynamic hard selling entrepreneurial initiatives which violate the medical professional code of practice and frown by the medical fraternity. The application for licence renewal was temporarily suspended for non compliance according to key informants. Yet, this boutique private health care facility concerned continued to operate its business in the metropolitan city for almost a year without a licence in spite of its gross contraventions and violations. It was not until the political intervention of the "invisible hands" which had graciously provided the renewal of the licence against the spirits and objectives of the legislation and to the dismay of the enforcement agency (personal communication).

Enforcement Capacity of MOH.

Regulatory intervention needs an enforcement capacity (Salamon, 1989). Under Part XVI of Act 586 which encompasses Section 87 to Section 100 provides adequate and comprehensive provisions of enforcement capacity. This among others includes the power to enter and inspect, power to search and seize, search and seizure without warrant, power to seal and mandatory information disclosure and investigation. However to facilitate effective enforcement capacity the MOH needs adequate resources in terms of manpower and the adequate information to regulate the medical practice in the corporate private hospitals. Findings at the Private Practice Unit, MOH on 6^{th} May, 2010 indicated that there were 13 doctors posts filled out of the budgeted 18 doctor posts, doing the processing of applications, inspection, licensing and enforcement works as illustrated in Table 3. These enforcement officers are supported by 12 senior nursing staff comprising of matrons and nursing sisters looking into compliance of the

Table 3: Enforcement manpower at the Private Practice Unit,MOH, as at 6 May, 2010.

Category of Staff	Number of Staff
1. Doctors	13
2. Nursing Staff	12
3. Paramedic & Support Staff	37
Total	62

Source:	MOH.	2010.

Table 4: Manpower at the Private Practice Unit, Medical & Health Wilayah Persekutuan, Kuala Lumpur asat 5 April, 2011.

Category of Staff	Number of Staff	
1. Doctors	5	
2. Nursing Staff	3	
3. Medical Assistant	4	
Total	12	

Source: MOH, 2011.

nursing staffing, manpower requirements and patient's safety measures under the Regulations. Besides, there were 37 other paramedic and administrative staff supporting the enforcement capacity.

Through key informant perceptions at the Private Practice Unit, MOH, the processing of applications, inspections and evaluations for licensing and enforcement required meticulous, rigorous and complex work. With the present manpower resource capacity, the enforcement team had been overstretched and over stressed physically and mentally covering the whole nationwide. The Private Practice Unit covers nationally all private healthcare facilities and services including the numerous private medical clinics. While there is an enforcement team at the state level to support the main enforcement team at MOH, it is still also under capacity. For instance at the Private Practice Unit, Medical and Health, Wilayah Persekutuan Kuala Lumpur, there were a total of 12 enforcement staff of which 5 are doctors, 4 Medical Assistants (now designated as Assistant Medical Officers), 1 Matron and 2 Nursing Sister as shown in Table 4. With the extensive proliferation of private hospitals, ambulatory care centres and other private healthcare facilities, the enforcement capacity is crucial.

The study reveals that the severely under strength human resource capacity and the over stretched regulatory enforcement staff in MOH had hampered the enforcement capacity. The enforcement team lead by a handful of senior medical officers while the rest of the medical officers are new and inexperienced entrusted to do the insurmountable enforcement work of regulating 288 licensed private healthcare facilities and services nationwide excluding the numerous medical and dental clinics (MOH,2008).

CONCLUSIONS

The preliminary findings of this study reveals that the Act 586 and its Regulation 2006 provides adequate provisions to address the policy makers' concerns to achieve the national objectives of accessibility, affordability, equity and quality healthcare in the private health sector. However in reality it remains an insurmountable challenge for the regulatory intervention to have the desired effect on the behaviour of the MOH as a regulator and the regulated corporate private hospitals in terms of compliance. Besides, it is also a daunting task and challenge for the regulatory intervention to achieve its explicit original objectives. Further the findings indicate that full compliance of these regulated corporate private hospitals remained a challenge. The

inadequate human resource staffing and the necessary information required had hampered the regulatory enforcement capacity of the MOH. The desired effect has not been seen to be effective other than the mandatory approval and licensing of these facilities which are influential and well informed.

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