

To: Healthcare Planning and Development Office,
Food and Health Bureau,
19/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong.

Dear Sir,

Comments on the Consultation Document on “Regulation of Private Healthcare Facilities”

I support the regulation of private healthcare facilities through appropriate accreditation. Hong Kong Accreditation Service, being a government organisation, enjoyed a high reputation in the international arena. It is known and respected for the degree of rigor of the assessments HKAS conducted. Seeking accreditation from HKAS should be encouraged as overseas accreditation bodies may not be familiar with the legislations and norms of Hong Kong and many local facilities have the perception that it is easier to be accredited by overseas accreditation bodies. Please find below my personal views / comments on the captioned consultation document:

1. Private healthcare facilities (PHFs), including private hospitals, ambulatory medical centers and clinics, embrace a wide range of privately-owned facilities providing medical diagnosis and treatment. Please clarify if this definition includes private medical testing laboratories which provide essential information to help in medical diagnosis and their service output subsequently affects the clinical management of patients and the length of stay in hospitals.
2. The medical clinics operated by medical groups and individuals are currently not under direct statutory control beyond regulation of individuals' professional practice. As mentioned on pg 6 of the document, some of these ordinances are outdated and have outlived their usefulness. The practice of solely relying on the ethic and self-discipline of doctors coupled with sanctions against those breaching professional conduct via the Medical Council under the Medical Registration Ordinance calls for change. Many of these clinics have associated medical testing laboratories or imaging centers, these facilities should also be suitably regulated in order to

strengthen the whole healthcare infrastructure. Registered medical laboratory technologists should be employed in all medical premises where laboratory testing is involved, not only in pathology testing laboratories. Additional training with respect to the specific task(s) associated with the services provided in the medical premises should also be provided to all employees no matter what prior qualification is held. Employing registered medical technologists is only the minimum requirement since basic medical laboratory science training provided the basic training in laboratory operation including appropriate laboratory biosafety, continuous professional development and training with respect to techniques and precautions necessary for the specific procedures performed must also be required.

3. Regulation of facilities providing medical services under the management of incorporated bodies is supported. Medical testing laboratories and imaging centers operated under the management of these incorporated bodies should also be included in the proposed regulation. This was not clear in the consultation document. Results of these diagnostic services may have serious implication to a patient and could lead to requirement of further healthcare.
4. In the document, hospital accreditation is proposed to be mandatory for private hospitals. This proposed requirement is supported. The focus of hospital accreditation is however different from specific accreditation applicable to laboratories, or to imaging diagnostic centers. Hospital accreditation is more directed to the operation of a quality system, patient's perception of customer service and interdepartmental cooperation. It ensures that a quality system is in operation at various departments, but its assessment has limited coverage on the technical competence of a laboratory or an imaging center in providing reliable test results and clinical interpretation. Separate laboratory accreditation or accreditation of the imaging center is still required on top of hospital accreditation.
5. To ensure clinical quality of PHFs, one of the six regulatory aspects is to prescribe standards on service delivery and care process for compliance of all PHFs. The so called "prescribed standards" had to be specific and directed to specific aspects of that medical profession, the "prescribed standards" should not be limited to only establishing a quality system, for instance, to ISO9000. Establishment of a quality system is only part of the requirements of applicable ISO standards (e.g. ISO15189) specifically written for operation of a medical laboratory or a medical diagnostic imaging centre. ISO15189, an internationally recognized accreditation standard specifically written for medical laboratories, coupled with specific accreditation

requirements prepared for respective disciplines (in the form of supplementary criteria) would be appropriate for use in accrediting diagnostic services in disciplines such as clinical physiology, medical imaging or medical physics. Operation in accordance to both the management requirements and specific technical requirements is necessary to ensure confidence in the quality of service provided. Otherwise garbage-in-garbage-out, this will have adverse impact on the whole healthcare infrastructure.

6. Committees to be appointed on page 15 – if the definition of PHFs include not only private hospitals, there should also be an independent committee on complaints against all types of private healthcare facilities, not only against the private hospitals.
7. The survey to be conducted to assess the number and types of private healthcare facilities that might be affected by the new regulatory regime (on page 16) should be as detailed as possible so that it also includes the assessment on the number of private medical testing laboratories, the number of facilities that bear the name of testing laboratories but only carry out specimen collection, the number of imaging diagnostic centers that provide comprehensive imaging procedures, the number of facilities that provide only simple X- ray, the number of facilities that provide both pathology testing and X-ray services.

Best regards,

(These are my personal views; please keep my name anonymous if my comments are to be published.)