



MINISTRY OF HEALTH
SINGAPORE

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MOH Circular No. 13/2021

1 February 2021

Licensees of Nursing Homes, Hospitals, Medical Clinics and Clinical Laboratories

PRIVATE HOSPITALS AND MEDICAL CLINICS (AMENDMENT) REGULATIONS 2021

MOH has introduced new regulatory requirements under the Private Hospitals and Medical Clinics (PHMC) (Amendment) Regulations 2021 which will come into operation on 1 May 2021. These new requirements have been promulgated to address patient safety issues and ensure minimum standards of care are met in certain licensed premises in the interim period before the Healthcare Services Act (HCSA) is rolled out in phases starting from September 2021.

2. A summary of the new requirements is as follows:
- a) A new Regulation 14A requires **nursing home licensees** to take all reasonable steps to ensure that their patients are provided with appropriate nursing care, and to ensure the safety and wellbeing, and protect the privacy, of every nursing home patient.
 - b) A new Regulation 29A requires **hospital licensees** to put systems in place to support their clinicians to ensure appropriate review of and follow-up on radiological test results.
 - c) A new category under the Second and Third Schedules provides for the regulation of organ transplant services for **hospital and clinic licensees** under the PHMC Act.
 - d) A new category under the Second, Third and Fifth Schedules provides for the regulation of pre-implantation genetic testing for monogenic/single gene defects and chromosomal structural rearrangement services for **clinical laboratory, hospital and clinic licensees** under the PHMC Act.



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- e) A revision to Regulation 56C(4)(b) removes the requirement for the person appointed to oversee provision of Collaborative Prescribing (CP) Services to be an employee of the licensee.

a) New Regulation 14A

3. The new Regulation 14A under the PHMC (Amendment) Regulations applies to all nursing home licensees. Nursing home licensees must ensure that every patient resident in the nursing home is provided with reasonable care, safety, and privacy. This new Regulation does not override any of the licensee's obligations under other written law (e.g. Mental Capacity Act).

4. Nursing home licensees should continue to implement and meet its requirements in the 2015 Licensing Terms and Conditions for Nursing Homes, which provide minimum standards for licensees to discharge their duties under this new regulation.

b) New Regulation 29A

5. MOH has received feedback regarding reporting requirements for radiological results following the case of *Noor Azlin bte Abdul Rahman v Changi General Hospital Pte Ltd and others* [2019] SGCA 13. Pending implementation of HCSA, Regulation 29A imposes an obligation on hospital licensees to support their clinicians and registered patients by having in place systems and processes that ensure appropriate review of and follow-up on all radiological findings¹.

6. Our intent is to ensure that there is a medical practitioner assigned to act on the patient's results. MOH does not intend to prescribe how this may be done and hospitals are free to set up their own workflow that will ensure the timely review and follow-ups of radiological findings for patients seeking treatment at the hospital, so as to safeguard patient safety and welfare. The desired outcome is that the requesting doctor (or another designated doctor) and/or their clinical team are to review the report findings regardless of the results received², and act upon them as appropriate, in accordance with the institution's relevant standard operating procedures and policies relating to classification of results and results reporting. This applies regardless of whether the patient may have access to the results through other avenues (e.g. HealthHub). As what constitutes "undue delay" needs to be assessed on an individual-patient basis, MOH will not be prescribing any specific timelines to this effect.

¹ Radiology modalities will include (and are not limited to): plain radiography, mammography, bone densitometry, fluoroscopy, computed tomography, ultrasonography, bone densitometry and magnetic resonance imaging.

² This includes all forms of results, including normal/negative findings or any abnormal/positive findings.



c) Organ Transplant Services

7. To better ensure patient safety, organ transplant services will be included as a specialised procedure / special care service under the Second and Third Schedules of the PHMC Regulations³ applicable to hospital and clinic licensees. With effect from 1 May 2021, all hospital and medical clinic licensees intending to provide organ transplant services will need to seek approval from the Director of Medical Services (DMS) before providing this service. Regulatory Terms and Conditions (RTCs) which stipulate the minimum standards for the provision of Organ Transplant services will be imposed on licensees approved to provide these services. These requirements are in addition to, and do not replace, requirements under existing written law (e.g. the Human Organ Transplant Act). The RTCs will be circulated separately and posted on MOH's website.

d) Pre-implantation genetic testing for monogenic/single gene defects and chromosomal structural rearrangements

8. Pre-implantation genetic testing is currently regulated as part of Assisted Reproduction (AR) services, and AR Centres must seek the approval of DMS before providing pre-implantation genetic testing / screening services. However, there are currently no specific technical requirements for these services.

9. With effect from 1 May 2021, pre-implantation genetic testing for monogenic/single gene defects (PGT-M) and chromosomal structural rearrangements (PGT-SR)⁴ will be added as a specialised procedure / special care service / specialised test specified in the Second, Third and Fifth Schedules of the PHMC Regulations applicable to hospital, clinic and clinical laboratory licensees. This means that hospitals, medical clinics and clinical laboratories that intend to provide PGT-M and/or PGT-SR will have to seek the approval of DMS to do so. For clarity, all licensed hospitals and medical clinics approved to provide AR services will have to seek separate approval from DMS to provide PGT-M and/or PGT-SR services. The RTCs which stipulate the requisite clinical and technical standards relating to the provision of PGT-M and PGT-SR will be imposed on licensees approved to provide these services. The RTCs will be circulated separately and posted on MOH's website.

³ In the Second Schedule, it is referred to as "organ transplant services, including transplant-related clinical services. In the Third Schedule, it is referred to as "transplant-related clinical services".

⁴ Which is used when one of both parents are patients or carriers of a serious genetic or chromosomal disorder and are at risk of transmitting that inheritable disease to their offspring.

e) Removal of requirement for the appointed person overseeing the provision of Collaborative Prescribing (CP) Services to be an employee of the licensee

10. In preparation for the extension of CP Services to the community setting (i.e. PHMC Act-licensed Community Hospitals and Nursing Homes), MOH will remove the requirement for the appointed person overseeing the provision of CP Services to be an employee of the licensee. The specific requirements for the appointed person stipulated in the Conditions for Provision of CP Service Imposed Pursuant to Regulation 56C(3)(a) of the PHMC Regulations have also been revised to reflect the amended requirement (**Annex A⁵**). This is to provide more flexibility in the appointment of such a suitably competent person, as long as there is proper oversight of CP services within the institution.

Implementation of the Amendments

11. The PHMC (Amendment) Regulations 2021 will take effect from 1 May 2021. The relevant RTCs may be accessed at <https://www.moh.gov.sg/licensing-and-regulation/regulations-guidelines-and-circulars>. Providers that are currently providing the services that have been added to the PHMCR Schedules (i.e. Organ Transplant, PGT-M, and/or PGT-SR) will need to seek approval from MOH to provide these services. Providers of Organ Transplant Services should submit your application no later than **28 February 2021**. Providers of PGT-M and/or PGT-SR services should submit your application no later than **31 March 2021**. Further details are stipulated in the covering circulars for the respective RTCs. **From 1 May 2021, providers without the requisite approval from MOH are not permitted to continue with the provision of these services.** Please contact us at elis@moh.gov.sg to submit your application. Should you require further clarification, please send us your queries to elis@moh.gov.sg as well.

Thank you.

Yours faithfully



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⁵ Please refer to Clause 3.1.