

Health Services Act of the Maldives

CHAPTER ONE

Preamble

Preamble and Title

1. (a) This Act provides for the establishment of a national health services system, strengthen health services, define quality of health services, define procedures, guidelines and requirements to be followed by facilities in providing health services, define procedures, guidelines and requirements to be followed when providing services by employees working in health sector, and define rights and responsibilities of health service provider and health service user.
- (b) The Act shall be cited as “Health Services Act of the Maldives”.

Main Objective

2. The main objectives of this Act shall be to achieve the following;
 - (a) Establish a National Health Services System;
 - (b) Define guidelines and standards to be followed by health service providers in providing health services in the Maldives;
 - (c) Ensure sustainability of services, equipment's, schemes and health service establishments provided by the state for the benefit of public,
 - (d) Ensure that health services provided by the State is accessible to all citizens; and ensure stability and sustainability of these services;
 - (e) Ensure that health services provided by private health service providers are accessible to all citizens; and ensure stability and sustainability of these services;

- (f) Protect the rights of and define the responsibilities of health service providers, health establishments, their employees and users of such providers and establishments.
- (g) Establish an effective mechanism to monitor and ensure that health service providers in Maldives maintain standards stipulated by this Act and Regulations made hereunder.

**Administration
of the Act**

- 3. (a) The Minister shall be held accountable at the highest fraction the administration and enforcement of this Act.
- (b) The State shall provide funding and resources necessary for the fulfilment of duties stipulated under subsection (a).

**Duties of the
minister**

- 4. Responsibilities and obligations undertaken by the Minister in order to administrate, enforce and implement actions stipulated under this Act shall include the following;
 - (a) To make adequate arrangements for the implementation of the State Health System stipulated under this Act and ensure its' effective implementation.
 - (b) Set guidelines for the safe maintenance of State set resources for provision of health care.
 - (c) Develop and ensure implementation of plans to build sustainable human resource capacity in health service provision.
 - (d) Develop a mechanism to ensure that all State health establishments provide health care to citizens in an equitable manner
 - (e) Ensure that health services provided at State health establishments are sustainable and are in accordance to laws and regulations.
 - (f) Ensure that primary health care services are available at all inhabited islands of the Maldives and that services are expanded and new services are introduced according to a

systematic plan;

- (g) Establish a mechanism to ensure that the provision of health services by private health service providers is in accordance with laws and regulations.
- (h) Establish a mechanism to ensure the quality and safety of health services provided in the Maldives;
- (i) Ensure that health services provided by the State are affordable to all citizens; and ensure quality and safety of these services;
- (j) Ensure that health services provided by the State are not services provided with the primary intent of generating economic profit.

Powers of the Minister

- 5. (a) Powers undertaken by the Minister in order to administrate, enforce and implement actions stipulated under this Act shall include the following;
 - (1) Take necessary actions for the performance of responsibilities stated in Section 4 of this Act personally or by delegation of power.
 - (2) To delegate specific powers and responsibilities under this Act to a category of people, or people in a distinct positions rather than an individual;
- (b) The delegation of power to a person or authority does not impede the Minister from executing these powers himself.
- (c) The Minister has the power to establish and enforce rules and regulations for the administration and implementation of this Act.

National Health Services System

- 6. (a) The National Health Service System stated in this Act refers to health care services provided by Government and private health establishments. The purpose of this system is to provide accessible, affordable, safe and quality health services to citizens across the country in a sustainable manner.

- (b) The Ministry shall collaborate with concerned authorities to develop and publish a long term master plan highlighting the methods for establishment and development of the health sector and national health services system.
- (c) The national health services system should be implemented as per the master plan mentioned in subsection (b) of this section.

**Composition of
the national
health services**

- 7. (a) As a minimum requirement, every inhabited island shall have a State setup primary health care facility.
- (b) Administrators of islands allocated for Industrial work and tourist resorts shall establish a system providing primary health care services to a level determined by the Ministry.
- (c) The main government- operated hospital in Male' City shall be at the highest level of health establishments under the National Health System. This hospital is deemed to be the national referral hospital.
- (d) Every City and Atoll of the Maldives shall have a Government-operated hospital. All government-operated health centers, clinics and other health service providers shall be operated, at the respective City or Atoll standard, directly by the City or Atoll Hospital, under the Minister's supervision, in accordance with this Act and regulations made hereunder.
- (e) In addition to Government set up health facilities such as hospitals and health centers, the Government may establish health facilities in joint partnership with private service providers or through private service providers in accordance with guideline defined by the Government.
- (f) Although subsection (d) states that all government operated health centers, clinics and other health service providers will be directly supervised by the respective hospital of the City or Atoll, the Minister will assign the administrator for health service providers in Male city.

Responsibilities of the head of the main Hospital of the City or Atoll.

8. Responsibilities and obligations undertaken by the head of government set up health facilities and head of supervising hospitals in Atolls and Cities include the following;
- (1) Operate and manage the main government hospital of the respective Atoll or City;
 - (2) Coordinate health related services of government operated health facilities in Cities or Atolls.
 - (3) Be answerable, to the Minister or any person determined by the Minister, regarding Government operated health facilities within Cities or Atolls and their services.
 - (4) In addition to responsibilities stated in paragraph (1) to (3), perform any other responsibilities determined by the Minister or any person assigned by the Minister.

Responsibilities of the Ministry

9. Establishing policies for health service provision, establishing framework for national health services system, providing financial and other resources for the national health services system, developing skilled employees required for health service provision, providing health services in a sustainable manner, maintaining all information related to health services, conducting research related to health services, and ensuring quality of health services are the responsibilities of the Ministry.

Acquiring machinery and resources required for provision of health services

10. (a) A procurement system shall be established and implemented under the Ministry or by a party assigned by the Ministry, to ensure quality and sustainable provision of machinery, equipment, medical consumables and other related resources to all Government operated health facilities within the national health services system.
- (b) If the procurement system stipulated in subsection (a) of this Section is implemented by the Ministry, Regulation made hereunder shall state the administration of the system and the categories and level of employees.

CHAPTER TWO

ADMINISTRATION OF HEALTH ESTABLISHMENTS

**Registration and
licensing**

11. (a) Any type of health service in Maldives shall be provided upon registration of the health establishment in accordance with this Act and the Regulations made hereunder, and upon obtaining a license, in accordance with this Act and Regulation made hereunder, to provide that service.
- (b) The health establishments and the services that require registration and licensing, and the grading criteria of those establishments and services shall be determined in the Regulation made hereunder.
- (c) The procedures for registering the services that require registration under this Act, and the procedures for obtaining the license shall be determined in the Regulation made hereunder.
- (d) Registration under this Act shall be for the health establishments. Licensing under this Act shall be for the services provided from those establishments. Registration of Health Professionals working in the profession and licensing of Professionals for the respective profession shall be carried out under the relevant Legislation.

Registration

12. (a) Any kind of health service in Maldives shall only be provided upon registering the health establishment in the Ministry in accordance with the regulation made hereunder.
- (b) Application for the registration of health establishment as stated in subsection (a) of this section shall be made to the Ministry in accordance with the Regulation made hereunder.
- (c) Health establishments shall be registered after taking a registration fee, as determined in the Regulation made hereunder, has been paid.
- (d) No renewal is necessary for health establishments registered in the Ministry under this Act, except for the circumstances stated in subsection (e) of this Section.

- (e) Renewal of the registration issued to a health establishment shall be required if there is a change in the grade to which it was registered to. Or in the event where a new registration is allowed in the Regulation made hereunder for any health establishment whose registration has been revoked for any reason.
- (f) The procedures to be followed for registration and renewal of registration of health establishment shall be stated in the Regulation made hereunder.

Temporary suspension and cancellation of Registration

- 13. (a) The Ministry has the discretion to temporarily suspend the registration issued to a health establishment if any of the following occurs;
 - (1) One of the conditions for issuing license to the facility ceases to exist;
 - (2) Nonfulfillment of the standards, as determined in the Regulation made hereunder, to be followed in providing health services.
 - (3) Negligence by the health establishment causes harm to a person.
- (b) If a criminal offence is proved in a court proceeding with regard to any service provided by a registered health establishment and the crime occurred in the establishment , and if Ministry believes that offence occurred with the knowledge of the person or persons involved in the management or occurred without their knowledge due to the negligence of the of the person or persons involved in the management, then the Ministry has the discretion to cancel the registration issued to that establishment.
- (c) The temporary suspension or cancellation of the registration under this section shall be made in accordance with the procedures stated in the Regulation made hereunder.

Acquiring License

- 14. (a) Health facilities registered under Section 12 of this Act may only provide health services after obtaining a license as stated in this Act.

- (b) Application for license in accordance with subsection (a) shall be submitted to the Ministry as stated in the Regulation made hereunder.
- (c) Procedures for issuance of license and matters to be considered in issuing license, and a regulation describing any other procedure in relation to issuance of license shall be published in the Maldivian Government's Gazette within 180 days of coming into force of this Act.

Transitional matters in relation to registration and licensing

- 15. (a) Health establishments registered in the Ministry prior to the coming into force of this Act shall, in order to register and obtain license under this Act, apply to the Ministry within 180 days of coming into force of this Act.
- (b) The Ministry shall, in accordance with this Act and the Regulation made hereunder, make necessary arrangements to ensure the registration and issuance of license under subsection (a) of this Act.

Grading of licensed health facilities

- 16. (a) Health services that require registration and licensing as health services, and based on the health services to be provided by health establishments, the Ministry shall classify the health establishments and health services into levels. The standards to be considered for grading health establishments and health services into levels shall be published in the Maldivian Government's Gazette.
- (b) The first standards made under subsection (a) of this section upon the commencement of this Act shall be published in the Maldivian Government's Gazette within 120 days of the coming into force of this Act.
- (c) The levels determined under (a) of this section and the services to be provided under those levels of facilities shall be stated in the Regulation made hereunder.

- (d) If a health establishment intends to provide a service in addition to the services allowed to the bodies and facilities to who license for health service provision have been issued, that establishment shall, in accordance with this Act and the Regulation made hereunder, apply for permission for the provision of that service.

**Duration
License**

- of 17. Unless otherwise stated in this Act, the license to provide health services to the health establishments shall be for 5 years. A health establishment shall, 180 days prior to the expiration of the license issued to that facility, apply to the Ministry to renew that license as stated in this Act and the Regulation made hereunder.

Annual fee

18. (a) Each establishment issued with a license for the provision of health service shall pay an annual fee, as stated in this Act and the Regulation made hereunder, to the Ministry or any other body determined by the Ministry. The annual fee applicable to a facility is based on the level of the facility determined under this Act in accordance with the health services that are provided. The amount of annual fee that shall be paid in accordance with the level of health facility shall be stated in the Regulation made hereunder.
- (b) If the annual fee payable by the health establishment is not paid in accordance with the Regulation made hereunder, the annual fee shall be collected following payment of a fine as stated in the Regulation.

**Registration and
Licensing**

19. (a) Registration of health establishments and issuance of license shall be conducted by a Unit established in the Ministry for that purpose.
- (b) An Employee of the unit mentioned in subsection (a) of this section shall not engage in any activity which may cause a conflict of interest such as employment, consultancy, managing, and shareholding of a health service establishment.
- (c) An advisory committee of 5 (five) members shall be constituted by the Minister, within 90 days of commencement of this Act to advise the Unit stated in subsection (a) of this section on registration and licensing.

(d) The advisory committee constituted by the Minister, on issuance of license to health services, shall include the following members.

(1) A Medical doctor.

(2) A nurse with a qualification higher than diploma in the field of nursing;

(3) A personal with a qualification higher than a Diploma in the field of Medical Laboratory.

(5) A technical authoritative person from the Ministry.

(e) Responsibilities of the committee, guideline on administration of the committee and qualifications and duration of membership of the committee shall be determined by the Regulations made hereunder.

**Unregistered or
Unlicensed
Services**

20. (a) It is an offence to provide any type health services in the Maldives without registering and obtaining a license in accordance with this Act and regulations made hereunder.

(b) It is an offence to continue to provide services if the acquired permit has expired or is temporarily suspended or invalidated.

(c) The administrator of the health facility shall be liable for offences committed under subsection (a) and (b) of this section.

(d) Notwithstanding anything in subsection 3 of this Section, this Section does not prohibit actions taken against unregistered or unlicensed technical health care professional in accordance with laws and regulations.

- (e) Any person convicted of an offence in terms of Subsection (a) and (b) of this Section is liable on conviction to a fine between fine between Rf.50,000(fifty thousand) and Rf.1,000,000 (one million) or imprisonment for a period between 3 (three) months and 5 (five years).
- (f) If the Ministry knows that a health establishment is operating without registering or without obtaining a license or without renewal of the issued license, the Ministry has the discretionary power to give notice of immediate shut down and take necessary steps to shut down the establishment.

Ensuring that technical staff in health establishment are licensed and registered

- 21. (a) A health establishment or person licensed under this Act can provide a health service if such service is in accordance with the academic and technical requirements under relevant laws and regulations and through persons licensed under relevant laws and regulations.
- (b) When applying for license to provide health services, the health establishment should have adequate technical staff required to provide the prescribed services. The said technical staff must be registered in the relevant council or board and must have a valid license to practice in the skilled area.
- (c) Health establishments licensed under this Act shall maintain a registry of all skilled staff and other employees. The administration shall ensure that all skilled staff employed at the health establishment is registered under relevant laws and regulations to practice in the establishment.
- (d) Any person employing a staff contravening subsection (b) and (c) of this Section is guilty of an offence.
- (e) Any person convicted of an offence in terms of Subsection (d) of this Section is liable on conviction to a fine between MVR50, 000/- (Fifty thousand) and MVR.100, 0000/- (One Million).

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| Scope of health services provided by the Government | 22. Services introduced at government-operated health establishments shall be introduced in accordance to government policies and the National Development Framework. |
| Usage of new Technology | 23. Public access to newly adopted Health services, treatments or medical technology in Maldives shall be given in accordance with rules and regulations made hereunder. |

CHAPTER THREE

HEALTH SERVICES' SAFETY AND QUALITY ASSURANCE SYSTEM

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| Commissioner of Quality Assurance | <p>24. (a) In ensuring the safety and quality of health care provided in Maldives, a person shall be assigned to the post entitled "Commissioner of Quality Assurance" who, in accordance with this Act, search inspect health service establishments and take necessary actions against such to ensure that they abide by rules and regulations, guidelines, procedures and standards in this Act and any pursuant rule.</p> <p>(b) The Civil Service commission shall be responsible for appointing a candidate for the post of Commissioner of Quality Assurance. The position of "Commissioner of Quality Assurance" is a civil service position equivalent to a Director General position. However, in addition to the general qualifications stated under the Civil Service Act, the person appointed to the post must have a Master's Degree in the Health field.</p> <p>(c) The Minister shall provide human resources and facilities essential for the fulfilment of the Commissioner of Quality Assurance's duties.</p> <p>(d) Employees stated in subsection (c) of this subsection shall not work in in any post which may conflict with their job responsibilities. An adequate exclusive job allowance shall be provided for such employees.</p> |
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**Powers and
duties of the
Commissioner.**

25. The duties of the Commissioner of the Quality Assurance are stated below.
- (a) To establish standards and procedures to ensure the quality of the health services and the safety of users and service providers.
 - (b) To ensure that standards and procedures established to enhance the quality of the health services and the safety of users and service providers are comprehensive and revised.
 - (c) To ensure that health establishments are set up in accordance with rules and regulations.
 - (d) To ensure that services provided by health establishments are in accordance with regulations and standards.
 - (e) To ensure that technical staff of health establishments are performing in accordance with established standards and rules.
 - (f) To send for inspections, entry and search of health establishments and notify on required rectification and in case of failure to comply with notices to take actions in accordance with this Act and regulations made hereunder.
 - (g) To impartially hear, investigate and report to the Minister on any complains about the health care services.
 - (h) To investigate and report any incidents of serious injury or medical negligence at health establishments to the related board or council and the Minister.
 - (i) To establish and implement a system for National Health Services Accreditation.

Search

26. (a) An employee searching a health establishment, on the authority of the Commissioner shall, pursuant to this Act, have the following powers.

- (1) To enter and search health establishments with or without prior notice.
- (2) To collect information by meeting and interviewing employees and staff at the health establishment.
- (3) To investigate and collect samples from equipment used at the health establishment in order to analyze the service of the establishment, quality and safety of the said equipment.
- (4) To examine and copy all records and documentations at the health facility.
- (5) If necessary, to summon and procure statement from witnesses and informants.
- (6) To obtain any other required information.

(b) The regulation made hereunder shall establish the procedural guidelines to be followed by the commissioner or authorized person in entry and search of health establishments.

(c) The power of the Commissioner or any person authorized by the commissioner to search health establishments under subsection (a) of this section is granted with respect to the Commissioner's duties stated in section 25 of this Act. This does not include the power to conduct criminal investigations.

(d) During the course of search, if the commissioner or authorized person has reasonable evidence to believe that a crime had been committed, a crime is being committed or is about to be committed, it shall be reported to the relevant authority in accordance with the relevant laws and regulations. The investigation shall be committed by the said relevant authority.

**Co-operating
with the
commissioner**

27. (a) Health establishments shall co-operate with the commissioner in fulfilling his duties. It is an offence to obstruct such duties.

- (b) Any person convicted of an offence in terms of Subsection (a) of this Section is liable on conviction to a fine between MVR.1,000/- (One thousand) and MVR.100,000/- (One lakh).

CHAPTER 4

RIGHTS AND DUTIES OF USERS AND HEALTH ESTABLISHMENTS

Services to be provided at health establishments

28. All services classified in the regulation made hereunder, as requirements of a particular category of Health service establishment shall be available from each Health service establishment belonging to that category.

Full disclosure of information to the User

29. (a) The following information shall be fully disclosed to the User by the Health service provider.
- (1) Health status of the User.
 - (2) The range of diagnostic procedures and treatment options available to the user;
 - (3) Procedures that are not available at the facility but that may be carried out to treat or diagnose the health status of the User.
 - (4) Necessary information on the benefits, risks and consequences generally associated with each option for the user to decide between the treatments options available.
 - (5) Estimated costs and the time taken for the service.
 - (6) The user's right to refuse health services Subject to Section 31 of this Act, and explain the implications and risks of such refusal.

- (b) Where the disclosure of such information would be contrary to the best interest of the user, the service provider must provide the information stated in the subsection (a) to the user's guardian or to a mandated person by the user.
- (c) If the User is under 18 year of age, Service Provider shall provide the information stated in subsection (a) to the user's guardian.
- (d) The information stated in subsection (a) shall be provided in a manner which takes in to account the user's level of literacy.
- (e) If the User was given an inpatient service or any other services in a health establishment, the health establishment must provide a statement containing the details of services to the user or the guardian or the mandated person.

Consent of User

- 30. (a) Subject to section 31 of this Act, a health service can only be provided with the informed consent of the user.
- (b) The Regulation made hereunder shall state the situations where written consent of the user must be obtained.
- (c) With the exception of section 31 and where written consent must be obtained, where the user does not object, it shall be deemed that the user gave consent for the service.
- (d) Subject to subsection (e), the guardian shall provide consent for users under 18 years of age.
- (e) If the user is between 15 and 18 years of age, the user's consent must be obtained in addition to the guardian's consent before providing the service.
- (f) It is a duty of the Service provider to obtain the consent from the user before giving the service.

- (g) For the purposes of this Section “informed consent” means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in Section 29 of this Act.

**Circumstances
where Health
Service can be
provided
without consent**

31. (a) Subject to Section 30, a service provider may provide a health service without the user’s informed consent under the following situations.

- (1) Where the user is incapable to provide the consent due to the health status, the mandated person by the user provides consent.
- (2) Where the user is unable to give informed consent due to the health status and no person is mandated or authorized in writing to give such consent, legal guardian or parent provides consent.
- (3) The provision of health service without informed consent is authorized in terms of any law or a court order.
- (4) Where the Head of the public health protection authority finds that failure to treat the user will result in a serious risk to public health.
- (5) Any delay in the provision of the health service to the user might result in in his or her death or irreversible damage to his or her health.

- (b) The procedures to obtain consent under subsection (a) 1 and 2 and the guidelines to be followed by the service provider under subsection (a), paragraph 4 and 5 shall be stated in the Regulation made hereunder.

**Health service
for the purpose
of clinical trial or
medical
research.**

32. (a) If the service provider wishes to provide the service as a clinical trial or for medical research purposes, such services shall be provided in accordance with the Regulation made hereunder.

		(b)	Before a health establishment provides a health service for clinical trial or medical research purposes to any user, the health establishment must inform the user and obtain the user's informed consent.
Health service for health and academic research	33.	(a)	Health and academic research relevant to the health services in the Maldives may only be carried out after obtaining permits in accordance with this Act and regulations made hereunder.
		(b)	There shall exist a technical and ethical committee to overview health and academic research carried out in the Maldives.
Rights of the user	34.	(a)	The right to obtain all the services provided by the health establishment at their finest level.
		(b)	The right to receive the detailed information as per section 29 of this Act.
		(c)	Subject to section 31 of this Act, in all other situations the user has the right to refuse services.
		(d)	Right to seek second opinion from a doctor or a health service provider.
		(e)	Subject to section 31 of this Act, user has the right to participate in the decision making process in regard to the user's treatment.
Duties of the service provider	35.	(a)	It is the duty of the service provider to ensure that the right of the user is guaranteed under Section 34 of this Act.
		(b)	Where the consent is given by a third party instead of the user, the service provider must consult with the user prior to treatment,
		(c)	Subject to Section 30 of this Act, in the circumstances where the user does not have the legal capacity to give consent, if the user understands, the service provider shall provide the information in accordance with Section 29 of this Act.

- (d) If the user is unable to participate in the decision making process due to the health status of the user, and if the knowledge of the information does not impose a health risk to the user, the information listed in section 29 shall be provided to the user at the appropriate time after the treatment is given.
- (e) Service provider shall ensure that the service provided to the user is the appropriate service based on national and technical standards and evidence.

Health Service without consent of the user

- 36. (a) If the user has been admitted without the consent of the user in accordance with any law or such other circumstance, the service provider shall inform the family of the user or if a foreign worker, his employee or Maldives Police Service within 24 hours of admission.
- (b) In a circumstance stated in subsection (a), if the user cannot be identified, the relevant government authority and Maldives Police Service shall be notified within 24 hours of admission.
- (c) Service provider shall establish the procedure to be followed where a patient has been brought to the facility in the circumstances stated in subsection (a), in accordance with the Ministry standards.

Publishing the price of the services

- 37. Health service provider shall publish and make readily available the costs of the services provided at the facility.

Information on the health service provider and the services provided

- 38. (a) Health establishments shall at all times keep visible the following information regarding the services provided at the health establishment.
 - (1) Types of services provided at the facility and the available services at the time;
 - (2) Arrangement of the service provided;
 - (3) Time that the services are provided;

- (4) Procedure to be followed to obtain service;
- (5) Procedure to file a complaint;
- (6) Any other relevant information stated in the Regulation made hereunder;
- (7) Any other relevant information that may be useful to the public in regard to the services provided at the facility.

(b) Guidelines on managing, sharing and reporting of essential information to be stored at the health establishments and in the health information systems established for the purpose shall be stipulated in the regulation made hereunder.

(c) The relevant information required to develop and provide services at the national health service system shall be shared with the Ministry in accordance to the guidelines of the Ministry.

**Managing
medical records**

39. (a) Service provider shall protect and manage the medical records of the users in accordance with the guidelines stated in the Regulation made hereunder. It is the duty of the person in charge of managing the facility to ensure that the records are managed in accordance with this Act and the Regulation made hereunder.
- (b) Procedure on compilation of records, maintenance standards and the procedure to be followed on maintaining the records shall be stipulated in the regulation made hereunder.

Confidentiality

40. (a) Information regarding a user's health status, treatments given or may be given, services received and any other such information concerning the User is confidential.
- (b) With the exception of the following circumstances, no person may disclose any information contemplated in subsection (a) to a third party.

- (1) User consents to disclose such information in writing;
- (2) Authorized in terms of a court order;
- (3) Where any law requires such information to be disclosed, disclosing of such information to the prescribed person in the law;
- (4) Upon written request from an authorized person seeking any information of the user stored at the facility to the extent necessary for any legitimate purpose within the ordinary course and scope of his or her duties under this Act.
- (5) Any information of the user shall be disclosed to a party stated in this section or any other party as stipulated in the Regulation made hereunder.

(c) It is an offence to act in contrary to (b) of this section.

(d) Any person convicted of an offence in terms of subsection (b) of this section is liable on conviction to a fine between MVR10,000 (Ten Thousand) and MVR 100,000 (One Hundred Thousand). And for any repetition of the offence, the judge may in his discretion convict the offender to imprisonment to a term not exceeding 1 (one) year, in addition the fine.

Use of Medical records

41. Section 40 does not prevent a service provider to disclose such information of the user, to the extent necessary to any other health service provider in the interests of the user's treatment.

Access to health records by health service provider

42. (a) With the exception of the following circumstances, no person shall examine a user's health records.

- (1) To provide a service to the user by an authoritative person of the service provider;

- (2) Where an authorized person, with the authorization of the Research and Ethics committee of the Health Establishment requests for academic or research purpose;
- (3) Where an authorized person requests such information, for the purpose of revision and investigation to upgrading quality.
- (4) Where relevant laws and regulations require information for the purpose of statistics;
- (5) For the protection of the general public in accordance with the Law by an authorized person.
- (6) Information required for an insurance scheme for insurance purposes by the authorized person.

(b) Medical records of the patients shall not be accessible to all the employees of the service provider. Such records shall only be accessible to the authorized persons in the situations stated in (a) of this section.

(c) The procedure to access and obtain the medical records of the user shall be stipulated in the regulation made hereunder.

Protection of health records

43. (a) Health service providers must set up control measures for safekeeping of records and prevent accessibility to the records except for employees' permitted to do so under this Act and the regulation made hereunder.
- (b) It is an offence to commit any of the following;
- (1) Fails to perform a duty imposed on them in terms of section 39 (a) of this Act;
 - (2) Breach section 42 (a) or (b) of this Act;
 - (3) Dispose or destroy medical records of any user;

- (4) Amend or alter a medical record without permission;
- (5) Fail or omit to update or amend a medical record when required to do so;
- (6) provide false information to be included in a medical record;
- (7) Copy any part of a medical record without permission;
- (8) Connect the personal identification elements of a user's record with user's health condition records without permission;
- (9) Use medical records of any user for any purpose without permission;
- (10) Connect the computer systems with electronic medical records to any other system or network without permission;
- (11) Approach or modify a computer system or a programme on which user's records are stored electronically without permission.

(c) Any person convicted of an offence in terms of subsection (b) of this section is liable on conviction to a fine between MVR10, 000 (Ten Thousand) and MVR 100,000 (One Hundred Thousand). And for any repetition of the offence, the judge may in his discretion convict the offender to imprisonment to a term not exceeding 1 (one) year, in addition the fine.

(d) If the offences stated in this section is facilitated due to the negligence of the health establishment, it shall be fined between MVR50, 000 (fifty Thousand) and MVR 500,000 (Five Hundred Thousand). The Ministry may also suspend the license of the service provider for a specific period in accordance with the Regulation made hereunder.

Providing statistics of the service provider to the Ministry

44. (a) To monitor and publish statistics of the health services by using the information retained by health establishments, health establishments shall provide the information to the Ministry in accordance with the guidelines established under this Act.
- (b) Service provider shall collect and manage the information that needs to be provided to the Ministry in accordance to subsection (a) of this section.

Laying of complaints with regard to service

45. (a) The user has the right to lodge complains to the senior management of a health establishment with regard to a service received or a service unavailable.
- (b) Service provider must establish a procedure for the laying of complaints; communicate acknowledgment of the complaint laid and the mechanisms to investigate the complaint. The complaint must be investigated and communicated to the user.
- (c) The procedures for laying complaints must be displayed by all health establishments in a manner that is visible for any person entering the facility. And the service provider shall carry out relevant programs to aware the users.
- (d) If the complaint laid with regard to a service provided by a health establishment, cannot be investigated by the receiver, health establishment shall communicate to the user, as authorized within the scope of the law, to file the complaint at the relevant government authority.
- (e) If the health establishment does not provide a reply to the complaint, or if the user is not satisfied with the reply received, the user may within 30 (thirty) days of the decision, request the Ministry to look into the matter.
- (f) Subject to subsection (e), Ministry shall give a reply to the user within 30 (thirty) days of the complaint.

- (g) Subject to subsection (f), if the Ministry is unable to give a reply within 30 (thirty) days, the Ministry shall inform the user of such with reason. And the Ministry shall give a reply to the user as soon as possible.
- (h) Users who wish to lay a complaint shall follow the procedure laid down in the relevant guidelines.

Duties of users

46. All users who receive health services from a health establishments shall take the following responsibilities upon them;

- (a) Adhere to the rules and guidelines of the health establishment;
- (b) Provide accurate information pertaining to his or her health status to the health service provider and co-operate with service provider;
- (c) Communicate with service providers with dignity and respect;
- (d) Sign a release of liability form accepting responsibility of any risk that may arise if he or she refuses to accept the service or the recommended treatment.
- (e) Not to give warnings, threat or cause harm to the service provider.

Obstruct service

47. It is an offence to intentionally obstruct or prevent the work of a health establishment.

Non-discrimination

48. (a) A user shall not be discriminated based on race, nationality, color, gender, age, physical or mental disability, political or any other belief, financial status, family, birth place or any other.
- (b) Subject to subsection (a), it shall not be deemed a discrimination where a user is provided a specific service based on his or her health.

**Refuse to
provide the
service**

49. (a) As a general rule, the health establishment shall provide services to all the users in accordance to their respective guidelines. However, the health establishment has the right to refuse to provide a service to a user who verbally or by act, threatens any service provider and attempts to harm anyone, or warns to impose such harm, or physically, mentally or sexually causes harm.
- (b) Subject to subsection (a) of this section, where the service provider refuses to provide the service, it is a duty of the health establishment to assist the user to find another mode to obtain service.
- (c) The procedure to be followed in the situations prescribed in subsection (a) and (b) shall be stipulated in the Regulation made hereunder.

CHAPTER 5

RIGHTS AND RESPONSIBILITIES OF EMPLOYEES OF HEALTH ESTABLISHMENTS

**Guidelines for
Employees**

50. (a) Employees in the health service profession shall comply and respect the policies and code of conducts of the profession.
- (b) Employees in the health service profession shall put aside personal interests and prioritize the health professions' and national interest.
- (c) employees in the health services profession shall not discriminate against any user on account of the user's race, nationality, gender, age, mental and physical disability, political different in opinion, economic, family status, geographical factor, or any other characteristic when providing services.
- (d) All employees in the health services profession shall comply and respect all the regulations, norms and standards of their respective work place.

- (e) In order to ensure consistency in providing health services as stipulated in subsection (c), all employees in health services profession shall refrain from actions that create divisions and differences in opinion within the society.
- (f) All employees in health services profession must fully participate and co-operate in work conducted to increase and sustain public trust towards the health services profession.
- (g) All the employees in health services profession shall perform all the duties and responsibilities as may be required or prescribed to do under this Act or regulations made hereunder.

Remuneration and benefits given to employees

51. Health establishment must provide a safe workplace to all employees. The following benefits and equipment must be ensured to employees of health service providers.

- (a) Equipment required to provide health service safely;
- (b) Safety precautions and such equipment must be established in the workplace for the safety and protection of personals at work.
- (c) Remuneration given to the employees must be appropriate with respect to his/her job and responsibilities;
- (d) Appropriate healthcare must be ensured to an employee if the employee had an injury due to the work environment or while performing a job responsibility without any negligence of the employee;
- (e) There shall be an insurance scheme established under the guidelines of the ministry to indemnify substantial damages incurred by employees in health services profession in the course of employment.

Reporting of an illicit activity

52. A health establishment shall not take any actions against employees who report an illicit activity taking place at the health establishment to a relevant authority.

Obstructing a health service

53. (a) As health service is a fundamental service, any employee for any reason obstructs or hinders a health service or part of the service or encourages for such act as obstructing public's right for service, is guilty of an offence.
- (b) Any person convicted of an offence in terms of Subsection (a) of this Section is liable on conviction to a fine between MVR 10,000 and- (Ten Thousand Rufiyaa) and MVR 100,000/- (Hundred Thousand Rufiyaa).
- (c) If the service or part of the service was obstructed by an employee registered in a board or a council of health service profession, ministry must file a complaint against the employee in the respective place and the respective board or council must take action against the employee. If the employee who obstructed the service or part of the service was a staff not in the health service profession, the respective place where the act occurred must take action against the employee.

Employees must not be accountable for the action taken in good faith

54. Any employee working at a health establishment must not be held accountable for any incident where the employee takes an action or make a decision in good faith and care, considering the conditions and equipment provided.

CHAPTER 6

BLOOD SERVICES

Blood services

55. In accordance with the consultation of the National Blood Council, the Ministry shall establish standards and guidelines to, acquire blood, store blood, conduct blood related investigation and researches and guidelines to follow in blood transfusions.

National Center for blood transfusion services

56. Maldivian Blood Services shall be the main institution, under the Ministry, in the National Health Services System to provide blood transfusion services, acquire, store blood, conduct blood related investigations and research.

- Review of blood services** 57. Maldivian Blood Services shall establish national blood services mechanism in Government and Private health service centers and hospitals and formulate regulations to enforce the mechanism monitor and coordinate regulations.
- Granting Permit for blood services** 58. (a) Maldivian Blood Services shall determine the conditions and standards for issuing license to Government and private health centers and hospitals for the operation of blood services.
- (b) The license stated in subsection (a) will be issued by the units stated in section 19 (a) of this Act.
- National Blood Council** 59. (a) Minister shall establish a council entitled National Blood Council consisting of 5 (five) members, to determine policies for the blood services and to consult the minister on blood service related matters within 90 (ninety) days from coming into force of this Act.
- (b) The council stated in subsection (a) shall consist members from the following fields;
- (1) A Technical Authoritative member appointed by the Ministry
- (2) A Technical Authoritative officer from the Maldivian Blood Services;
- (3) A technical expert of blood services profession;
- (4) A specialized Medical Doctor in blood services or a Pathologist;
- (5) A member from a non-government organization that works to promote awareness on prevention of blood related diseases.
- (c) Council members are not entitled to any remuneration or benefits except for an allowance for the council meetings that they attend. The allowance stated in this section shall be determined by the Ministry of Finance and Territory.

- (d) The President of the Council shall be the technical authoritative member proposed by the Ministry. Where the President is unable to perform his/her duties, the President shall appoint a member within the council to do his/her duties.
- (e) The administrative work of the Council will be handled by the Ministry.
- (f) Appointment of members, term and prerequisites of membership and guidelines on conducting council meetings must be stipulated in the regulation made hereunder. The regulation shall also prescribe on operation of the council and powers and guidelines of the council.

**Ensuring safety
of blood**

- 60. (a) The standards and guidelines required to ensure a safe blood supply service in health establishments shall be stipulated in the regulation made hereunder.
- (b) Blood can only be regulated as a biological by a person mandated to regulate a biological. Guidelines and standards to ensure safety measures and good manufacturing practices in the processing of blood and division of blood component must be stipulated under the regulation made hereunder.

**Blood
transactions**

- 61. (a) Selling and trading blood to be used in health services is an offence.
- (b) To provide or receive any financial or material rewards to or by a blood donor, or a mediator or any other party involved in the process of blood donation is an offence.
- (c) A certificate or plaque given as appreciation and encouragement for blood donation, or a card that is given as a token to regular blood donors shall not be considered a financial or material reward as stated in subsection (b).
- (d) No fees shall be charged for blood transfusion services. However, this section does not prevent a fee to be taken for collection of blood, storage, testing and

other services.

- (e) Any person convicted of an offence in terms of Subsection (a) and (b) of this Section is liable on conviction to a fine between MVR 10,000 and- (Ten Thousand Rufiyaa) and MVR100, 000/- (Hundred Thousand Rufiyaa). And for any repetition of the offence, the judge may in his discretion convict the offender to imprisonment to a term not exceeding 1 (one) year, in addition the fine.

**Responsibilities
of blood donors**

- 62. (a) Any person who knows that he suffers or is a carrier of a disease transmissible through blood, or has been involved or has the habit of being involved in acts which may lead to diseases transmissible through blood shall not donate blood.
- (b) Any person who donated blood shall, at the earliest possible notify the health establishment where blood was donated, if the person becomes aware that the donated blood may be questionable or has a symptom of a disease transmissible through blood, or has a disease transmissible through blood.

CHAPTER 7

DRUGS USED IN THE NATIONAL HEALTH SERVICES SYSTEM

**Drugs for the use
of the National
Health Services
System**

- 63. (a) It is a responsibility of the ministry to obtain essential drugs and make it available to the users at a reasonable price.
- (b) Maldives Food and Drug Authority shall regulate and formulate regulations with regard to drugs, types of drugs and products used as such used in National Health Services System.
- (c) It is a responsibility of Maldives Food and Drug Authority to assist the ministry in identifying and eliminating hindrances in providing essential drugs as stated in subsection (a).

- (d) In order to ensure all drugs used in the national health services system are provided at a reasonable price, Ministry must determine a ceiling price for all drugs.

Importing the drugs needed for the National Health Service System.

- 64. (a) Drugs required for the health establishments shall be imported in accordance with the laws and regulations formulated with regard to importing drugs and as stipulated in this Act and regulations made hereunder.
- (b) It is an offence to import and sell drugs without a permit.
- (c) Any person convicted of an offence in terms of Subsection (b) of this Section is liable on conviction to a fine between MVR 10,000and- (Ten Thousand Rufiyaa) and MVR500, 000/- (Five Hundred Thousand Rufiyaa) and imprisonment for a term not exceeding one year.

Trade and Responsible use of drugs

- 65. (a) Pharmaceutical services maybe established in a health establishment in accordance with the laws and regulations formulated with regard to trading and consumption of drugs and as stipulated in this Act and regulations made hereunder.
- (b) Maldives Food and Drug Authority shall monitor the usage and dispensing of drugs and types of drugs by heath establishments, review low quality drugs and any harmful effects of such drugs.
- (c) Drugs sold imported or manufactured in Maldives for the purpose of national health services shall be safe and of good quality. And such shall be permitted and registered drugs by the Maldives food and drug authority.
- (d) Maldives food and drug authority shall formulate guidelines, standards and regulations to regulate drugs imported or manufactured in the Maldives for the purpose of National Health Services and formulate guidelines and standards.

- (e) To ensure the safety and quality of the drugs, Maldives Food and Drug Authority has the authorization to inspect and take samples for testing from health centers, hospitals, storages and other places that may store drugs, and pharmacies. And to obstruct this process is an offence.
- (f) Any person convicted of an offence in terms of Subsection (e) of this Section is liable on conviction to a fine between MVR 10,000/- (Ten Thousand Rufiyaa) and MVR50, 000/- (Fifty Thousand Rufiyaa) and imprisonment for a term not exceeding one year.
- (g) Trading expired drugs, or contaminated drugs or drugs with unknown substances or obscured labeled drugs and counterfeit drugs in the Maldives shall be an offence.
- (h) Any person convicted of an offence in terms of Subsection (g) of this Section is liable on conviction to a fine between MVR 10,000/- (Ten Thousand Rufiyaa) and MVR500,000/- (Five Hundred Thousand Rufiyaa) and imprisonment for a term not exceeding one year.

Drug registry

- 66. (a) Maldives Food and Drug Authority shall establish and publish a registry on Drugs permitted to be imported and sold in the Maldives for the purpose of national health services. The registry shall be updated and monitored regularly.
- (b) Maldives Food and Drug Authority shall establish and publish a registry on essential Drugs required for the national health services. The registry shall be updated and monitored regularly.
- (c) Regulations, guidelines and conditions for the registration of drugs shall be stipulated in the regulation made hereunder.
- 67. (a) In order to make policies regarding medicinal drugs, vaccines, products used as drugs and medical devices, and to consult the ministry with regard to formulation of regulations, the minister shall establish “National Pharmaceutical Board”. The administration of this board shall be Maldives Food and Drug Authority.

(b) The board stated in subsection (a) comprises of members from the following fields;

- (1) Three specialists in three different fields from the National Referral Hospital's clinic;
- (2) A representative of Health Protection Agency;
- (3) A Technical Authoritative member from the Ministry;
- (4) Head of Maldives Food and Drug Authority;
- (5) A representative from the National Drug Agency;
- (6) A representative from Maldives Customs Service;
- (7) A representative from Ministry of Economic Development;
- (8) Head of the pharmaceuticals of Maldives Food and Drug Authority (Pharmacist)

(c) Responsibilities of the board established under subsection (a), guidelines on the conduct of the board, term and prerequisites of membership must be stipulated in the regulation made hereunder.

CHAPTER 8

MISCELLANEOUS PROVISIONS

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| Permit for service establishment | 68. Application for a permit to provide health service under this Act must be made by a service user or a third party assigned by the service user. |
| Forensic investigation and postmortem | <p>69. (a) Health center or institution to conduct forensic investigation, postmortem and other such investigations within the National Health Service System shall be determined by the minister.</p> <p>(b) Investigations stipulated in subsection (s) shall be carried in accordance with the regulation made hereunder.</p> |
| General Offence | 70. Apart from all the offences stated under this Act, any person who breaches this Act, or takes any action in breach of this act, or any act done to breach this Act, and any offences stated under this Act where a penalty is not stated is guilty of an offence. Any person convicted of an offence in terms of this Section is liable on conviction to a fine between 10,000 (Ten Thousand Rufiyaa) and 100,000 Hundred Thousand Rufiyaa). |
| Protection to the employees who enforce the Act | 71. No action shall lie and no prosecution shall be brought or instituted against the Minister, or any officer or any person acting under the direction of the Minister for anything done or omitted to be done under this Act in good faith for carrying into effect the provisions of this Act. And he/she shall not bear responsibilities under the law or shari'ah; |
| formulation and enforcement of regulations | <p>72. (a) Unless stated otherwise stated in this Act, The Ministry shall formulate the regulations to enforce and implement this Act.</p> <p>(b) Unless otherwise stated under this Act, regulations under this Act must be formulated and published in the gazette within 180 (Hundred and Eighty) Days from coming into force of this Act.</p> |
| Commencement | 73. This law will come into effect 12 (Twelve) months from the date it's passed, ratified and published in the Government |

Gazette.

Definitions

74. Unless otherwise stated in this Act, the following words and terms shall have meaning assigned to them below:
- (a) "Health Service" means services provided to prevent and treat diseases or illness.
 - (b) "Minister" means the Minister appointed for the time being to enforce health sector policies;
 - (c) "Ministry" means a Ministry appointed for the time being to enforce health sector policies;
 - (d) "Basic health services" means minimum level of service determined by the ministry to be available at the inhabited islands or tourist or industrial islands.
 - (e) "Medical record" means information retained on paper or electronically in the course of treatment to the user inclusive of personal information, results of the investigations, findings, and treatments.
 - (f) "Person" means natural and legal personalities;
 - (g) "Blood" means human blood, components and elements of blood.
 - (h) "Drugs and types of drugs" means medical or alternative medicine or medicine and types of medicine used in traditional Maldivian medicine, medical gas vaccines and inclusive of biologicals;
 - (i) "Health information system" means a system which collects information on paper or electronically on services provided by health establishment or the operation of services at the establishments, or information on the establishment, or patients' information. This system will record other health information given or retired via community services or services such as mobile services provided by the establishment;

- (j) “National Accreditation System of Health Services” means the system that determines the qualification and classification of health establishments;
- (k) “Operator of the Health Establishment” means the person, under whose name the health establishment is registered;
- (l) “Procurement System” means the unit or section established in the Ministry or where the ministry determines otherwise, to supply medical devices, machineries, equipment and medical consumables required by the government owned health centers and hospitals;
- (m) “Category” means the classification given to the health establishments after the qualification process of such;
- (n) “Employees in the health establishment” means all the employees accountable to the Minister;
- (o) “Drugs” means medical and alternative medicine. Medical Drugs means any medicine and its bulk chemical prescribed by a doctor to be used for treatment. Alternative drugs means medicine used according to the guidelines of a respective discipline in treating a disease or illness;
- (p) “Public Health” means unless otherwise stated, for use of this Act, Public Health define as stated in the Act 7/2012 (Public Health Safety Act).