

การแพทย์ทางไกล: กระแสนิยมหรือความปกติใหม่ตลอดไป

(Telemedicine:
A Passing Fad or a Long-Term Paradigm Shift?)

Piraya Tamrongterakul, MD.

CEO & Co-founder, Chiiwii

Medical Director, MorDee



Creating O2O Telehealth Ecosystem for the People Across Thailand

Certified Telemedicine Provider by Ministry of Public Health



Telemedicine Platform Initiative of the Year by Healthcare Asia MedTech



Finalist 2022 ASEAN Innovation Awards  **AIBP**

2nd Prize Winner Best Health Influencer Campaign Award: Thailand Influencer Award 2022





- 33.8 million TrueMove H users and 21.2 million Dtac members (5.2m with Health, Beauty & Digital Trendy)
- 1,000 Software Engineers
- Highest cyber security & privacy protection
- Healthcare Ecosystem across CP Group



- 500+ medical specialist with more than 20 specialties
- Leading telemedicine platform
- Experience in Thai Market since 2017

Partnership between Leaders in Digital Tech & Telemedicine

Enabling HEALTHCARE Digital Transformation

MorDee for Consumers



500+ doctors & services on demand anywhere

MorDee Health Spaces



The 3rd place between Home & Hospitals

MorDee MedTech



IoT & Innovation enchainning digital & preventive health

MorDee for Hospitals



Telemedicine Solutions for Hospitals & Clinics

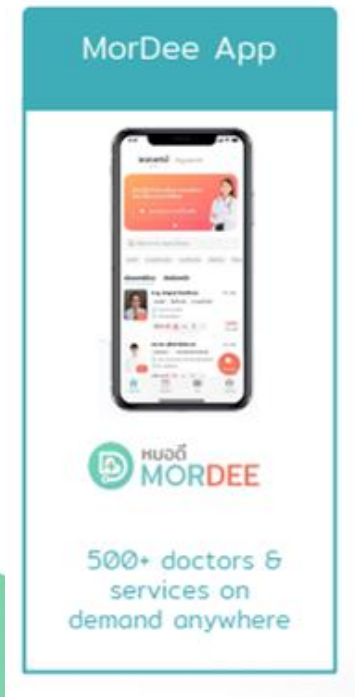
MorDee SAVER Smart EMS & ER



Helping patients even before reaching hospitals

Enabling HEALTHCARE Digital Transformation

Core Products & Services



หมวด
MORDEE

End-to-End **Telehealth** Solutions

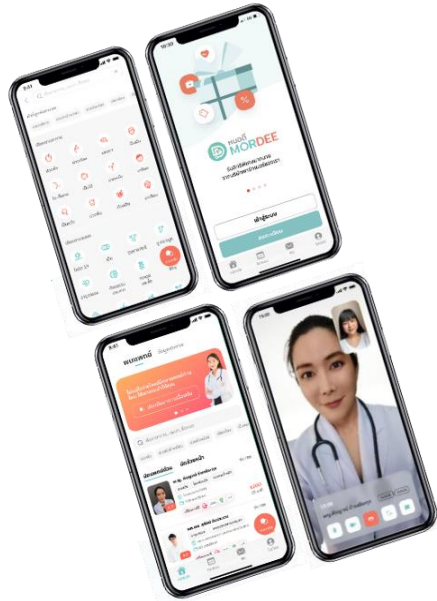
Certified Telemedicine Provider by Ministry of Public Health



Telemedicine Platform Initiative of the Year by Healthcare Asia MedTech AWARDS

HEALTHCARE ASIA
MED+TECH
AWARDS

End-to-end Telehealth Platform with Comprehensive Features



Virtual Consultation

- 500+ doctors from 20+ sub-specialties
- 24 x 7 access
- Electronics Health Record from doctors
- Secured payment via credit cards & PromptPay
- Direct e-claim with leading insurances & self-funded corporates
- Direct e-claim for National Health Coverage (NHSO)



Medication Delivery

- E-prescription from our doctors
- Delivery within 90 minutes after consultation
- Pharmacists ensuring the safe prescribing and dispensing of medication and call to advice patient about the proper use of medication after delivery.



Scan QR Code to download MorDee Application



On-site Vaccination & Health Check-up

- At-home vaccination and blood sample collection.
- On-site check-up and vaccination for corporates.



Referral Hospitals



Certified Telemedicine Provider

by the Ministry of Public Health

- Chiwiborirak Clinic: Located at Sukhumvit 89.



Our Doctors

High-quality-standard medical specialists



500+

Doctors & specialists from leading medical schools/ public/private hospitals



20+

Specialties & Sub-specialties

Covering most medical specialties, you can think of...



Internal medicine



Obstetric-Gynecology



Orthopedics



Physical & Rehabilitation



Otolaryngology



Psychiatry



Dermatology



Pediatrics



Ophthalmology



Nutrition & Wellness

And many more...

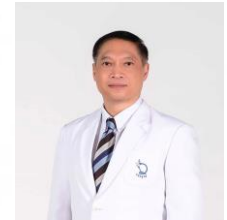
Medical Advisory Board



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Head of Otolaryngology head & Neck surgery department, Faculty of Medicine, Ramathibodi Hospital

ที่ปรึกษาราชวิทยาลัยโสต ศอ นาสิกแพทย์แห่งประเทศไทย



Dr. Sak Segkhoonthod

ที่ปรึกษาและรักษาการรองผู้อำนวยการ สำนักงานพัฒนาธุรกรรมทางอิเล็กทรอนิกส์ (ETDA Thailand)
อดีตผู้อำนวยการสำนักงานรัฐบาลอิเล็กทรอนิกส์ , กระทรวงไอซีที

Omnichannel Health Education



Online and On-site Health Education

- Communicate to patients about disease awareness, treatment and prevention via online media platform, webinar, pre-recorded in studio, or on-site workshop



Always-on Health Content

- Physicians' original health articles on our social media channels.



@mordeeapp



facebook.com/mordeeapp



@mordeeapp



mordeeapp.com



Health Education:

หน้าแรก คู่มือ MORDEE ข้อมูลแพทย์ ผู้สันทนงานบริการ



กิจกรรมและโปรแกรม บทความ สำหรับองค์กร En

บทความทั้งหมด

เรียงตามใหม่

ตาขาวระตุก ลางบอกเหตุ หรือ ลางบอกโรค?

ตาขาวระตุกคืออะไร? ลางบอกเหตุ หรือ ลางบอกโรค?

ตาขาวระตุกคืออะไร? ลางบอกเหตุ หรือ ลางบอกโรค?

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ตาขาวระตุกคืออะไร? ลางบอกเหตุ หรือ ลางบอกโรค?

5 งานอดิเรกที่คุ้มหมอนแฉะน้ำ เพื่อกายและใจที่ดี

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มะเร็งต่อมลูกหมาก รู้เร็ว รักษาทันเวลา

มะเร็งต่อมลูกหมาก รู้เร็ว รักษาทันเวลา

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มะเร็งต่อมลูกหมาก รู้เร็ว รักษาทันเวลา

คั่นน้องสาว!? รู้ทัน ป้องกัน โกลโรค

คั่นน้องสาว!? รู้ทัน ป้องกัน โกลโรค

คั่นน้องสาว!? รู้ทัน ป้องกัน โกลโรค

คั่นน้องสาว!? รู้ทัน ป้องกัน โกลโรค

กินอย่างไร ห่างไกลมาหาจนทะเลโรสิต

กินอย่างไร ห่างไกลมาหาจนทะเลโรสิต

กินอย่างไร ห่างไกลมาหาจนทะเลโรสิต

กินอย่างไร ห่างไกลมาหาจนทะเลโรสิต

ยาทาแก้คัน เลือกใช้อย่างไรดี?

ยาทาแก้คัน เลือกใช้อย่างไรดี?

ยาทาแก้คัน เลือกใช้อย่างไรดี?

ยาทาแก้คัน เลือกใช้อย่างไรดี?

รู้ทันอาการ บวมท้องแมงสาที่ไม่ปกติ

รู้ทันอาการ บวมท้องแมงสาที่ไม่ปกติ

รู้ทันอาการ บวมท้องแมงสาที่ไม่ปกติ

รู้ทันอาการ บวมท้องแมงสาที่ไม่ปกติ

ข้อดีของ "การล้างจมูก" ที่คุณอาจไม่เคยรู้

ข้อดีของ "การล้างจมูก" ที่คุณอาจไม่เคยรู้

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THAI HEALTH

รศ. พญ.เปรมจิต อึ้งกอนุ่น

แพทย์ผู้เชี่ยวชาญทางด้านโรคผิวหนัง



Interesting facts:



Downloaded = 300K+



Registered = 120K+



MAU = 30K+

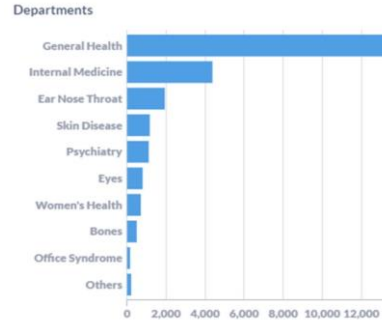


F:M = 60:40



Age range = 18-70 Peak 25-45

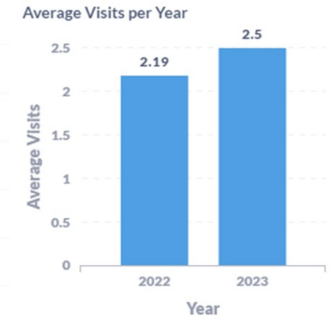
Top Departments



Top Diagnosis



Repeat users



Challenges and Concerns







Factors influencing the acceptance of telemedicine in the Philippines

Ardvin Kester S. Ong,^{a, b} , Yoshiki B. Kurata,^a , Sophia Alessandra D.G. Castro,^a ,
Jeanne Paulene B. De Leon,^a , Hazel V. Dela Rosa,^a , Alex Patricia J. Tomines,^a 

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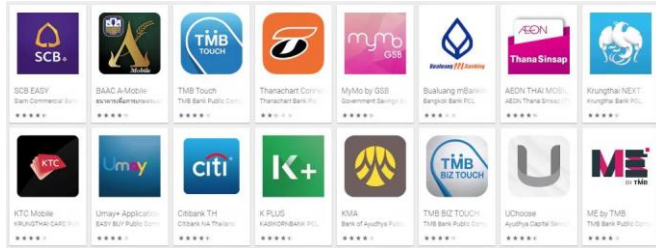
Abstract

Telemedicine refers to the use of technology to deliver medical care services remotely. Its utilization has been shown to increase access to healthcare services and bridge gaps to existing healthcare system issues during the COVID-19 pandemic. Kane and Gillis [5] explained how telemedicine services have grown by 44% over the past five years by its array of applications in radiology, psychiatry, pathology, emergency medicine, and different internal medicine subspecialties such as cardiology and neurology. Southeast Asian countries have the potential to accelerate the adoption of telemedicine [6]. According to Sabrina and Defi [7]; certain countries in the region exhibited a slow uptake in telemedicine utilization among healthcare providers due to a focus on the more ethical and clinical aspects of the system shown in twenty-four articles from certain SEA countries that contain telemedicine guidelines, in which 100% of the articles encompass guidelines involving clinical governance. However, despite the benefits of telemedicine and advancements in technology, it is not widely utilized in the Philippines [8].

A black and white photograph showing several people in business attire looking at and pointing to various charts and documents on a table. The image is partially obscured by a large red abstract shape.

ปัจจัยใดเป็นปัจจัยที่สำคัญที่จะส่งผลให้การแพทย์ทางไกล
หยุดหรือไปต่อได้ ในระบบสุขภาพของประเทศไทย?

Proper Regulations:



แอป **Mobile Banking** ของหลายๆ ธนาคารถือเป็นแอปพื้นฐานที่ต้องมีติดเครื่องกันแทบทุกคน โดยจะคอยช่วยอำนวยความสะดวกกับชีวิตประจำวันทั้งการจ่ายบิล โอนเงิน ถอนเงิน ATM หรือเช็คยอดเงิน ก็สามารถทำได้หมดบนแอปที่เดียว เพื่อเพิ่มความปลอดภัยธนาคารแห่งประเทศไทยเลยประกาศให้ทุกธนาคารมีมาตรฐานเดียวกันคือห้ามไม่ให้มือถือรุ่นเก่าๆ ที่ระบบไม่มีความปลอดภัย รวมถึงเครื่องที่ถูก root หรือ jailbreak มาหันเข้าใช้บริการแอป Mobile Banking ได้



ธนาคารแห่งประเทศไทยได้สังเกตเห็นความเสี่ยงต่างๆ ที่ผู้ใช้งานมีโอกาสได้รับทั้งโดยตรงและทางอ้อมจึงได้ออกมาตรการขั้นต้นด้านระบบ 12 ข้อดังนี้

มาตรการ 12 ข้อจากธนาคารแห่งประเทศไทย

1. **ไม่อนุญาต** ให้เครื่องที่ผ่านการ **root** หรือ **jailbreak** ใช้งานได้ เพื่อหลีกเลี่ยงผู้ไม่ประสงค์ดีเข้าถึงข้อมูล
2. **ไม่อนุญาต** ให้เครื่องใช้ OS หรือระบบปฏิบัติการล้าสมัยใช้งานแอปได้ (obsolete Operating System : OS) หรือช่องโหว่ร้ายแรงที่ประกาศจากหน่วยงานสากล
3. แอป **Mobile Banking** ต้องขอสิทธิ์เท่าที่จำเป็น และมีกระบวนการทบทวนสิทธิ์ดังกล่าวเป็นประจำ เพื่อป้องกันการละเมิดความเป็นส่วนตัวของผู้ใช้บริการ
4. ปกป้อง Source Code ส่วนสำคัญ เช่น การโอนเงิน การพิสูจน์ตัวตน ไม่ให้รั่วไหลจากแอป
5. ป้องกันการฝังข้อมูลสำคัญ หรือ Code ที่ไม่พึงประสงค์
6. เข้มงวดไฟล์ข้อมูล (Files Encryption) ที่จัดเก็บข้อมูลกันการรั่วไหล
7. **ไม่อนุญาต** ให้ใช้แอป **Mobile Banking** เวอร์ชันต่ำกว่าที่ผู้ให้บริการกำหนด
8. ป้องกันการโจมตีในลักษณะ DDoS ในระดับเครือข่าย เพื่อป้องกันระบบถูกโจมตีจนไม่สามารถใช้งานได้
9. ป้องกันการถูกดักจับหรือแก้ไขข้อมูลระหว่างการรับส่ง โดยต้องยืนยันตัวตนด้วยเทคนิค Certification Pinning หรือเทียบเท่า
10. ป้องกันการสวมรอยการเข้าใช้งานของลูกค้า (Session Hijacking)
11. ป้องกันการเข้าถึงเซิร์ฟเวอร์โดยไม่ได้รับอนุญาต เช่น การใช้ SQL Injection, Local File Inclusion หรือ Directory Traversal
12. ตรวจสอบและเตรียมรับมือหากแอปปลอมทั้งบน Google Play และ App Store

Government support:

ธนาคารแห่งประเทศไทย
BANK OF THAILAND

สบายใจ ทุกสถานการณ์ เหมือนมีธนาคารบนมือถือคุณ

5 เหตุผล ทำไมต้องมี “Mobile Banking”



- สะดวก** 24/7 ทำธุรกรรมได้ทุกที่ ทุกเวลา
- ง่าย** ไม่ว่าใครก็ใช้ได้ ไม่ซับซ้อน
- หลากหลาย** จะรับ โอน จ่าย เต็ม เขียยอด ได้หมด!
- ประหยัด** ค่าธรรมเนียมต่ำกว่าช่องทางอื่น
- ปลอดภัย** ใช้บริการได้อย่างมั่นใจในทุกสถานการณ์

เมื่อทำธุรกรรมผ่าน Mobile Banking ไม่ควรใช้ WIFI สาธารณะ เพื่อป้องกันภัยออนไลน์

สมัครได้ง่าย ๆ ตามช่องทางธนาคารของคุณ

ไม่ต้องต่อแถว

จ่ายที่ไหนก็ได้

ชำระเงินกู้ของธนาคารผ่าน **GHB ALL**

แอปเดียวครบจบ รวมทุกบริการ ธอส. ไว้ในมือคุณ

ดาวน์โหลดได้แล้ววันนี้



ดาวน์โหลดบน App Store | GET IT ON Google Play

02-645-9000 | f | t | y | GHBANK

การไฟฟ้านครหลวง Metropolitan Electricity Authority

จ่ายค่าไฟง่าย ๆ ผ่าน Mobile Banking **MEA** รวมทุกแอปธนาคาร

ไม่ต้องเดินทาง ลดความเสี่ยง COVID-19

แอปเด็ด โดนใจ หลากหลายช่องทางเพียงพอ **นอกวัน 24 ชม.**



MEASoft

User Education:



Mobile Banking
ใช้อย่างไรให้ปลอดภัย

-  ดาวน์โหลดแอปจากแหล่งที่น่าเชื่อถือ เช่น Apple Store, Google Play Store
-  ออกจากระบบทุกครั้งเมื่อเลิกใช้งาน
-  ทำรายการธุรกรรมด้วยตัวเอง
-  ไม่ติดตั้งระบบปฏิบัติการมือถือ
-  ไม่คลิก Link จาก SMS
-  ไม่ใช้ WiFi สาธารณะทำธุรกรรมการเงิน
-  ต้องรหัสผ่านให้ตายาย
-  ดูแลให้ท่านเป็นผู้ใช้จริงในบ้านให้สามารถรู้ Mobile Banking ได้อย่างถูกต้องและปลอดภัย

ที่มา : ศูนย์คุ้มครองผู้ใช้บริการทางการเงิน ธนาคารแห่งประเทศไทย

ANTI-FAKE NEWS CENTER ศูนย์ต่อต้านข่าวปลอม ประเทศไทย
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สิ่งที่คาดหวังให้เกิดขึ้นสำหรับการแพทย์ทางไกลในอนาคตสำหรับประเทศไทย?

Indonesia: New Indonesian Medical Council Regulation on Telemedicine Services During COVID-19 Pandemic

28 Jul 2020 • 9 minute read



On 29 April 2020, the Indonesian Medical Council (Konsil Kedokteran Indonesia) ("KKI") issued KKI Regulation No. 74 of 2020 on Clinical Authorities and Medical Treatment Through Telemedicine During the COVID-19 Pandemic ("KKI Regulation 74").

Key Takeaways of Telemedicine Services under KKI Regulation 74

1. In **emergency** situations, doctors and dentists who provide medical treatment through telemedicine services must instruct their patients to undergo direct (read: physical) medical treatment at the relevant healthcare facility.
2. Patients must provide their **general/informed consent** in accordance with the prevailing laws and regulations. KKI Regulation 74 does not elaborate on the context of the general/informed consent¹. In any case, this requirement must be read in conjunction with medical confidentiality principles. Any medical data of the patients collected through the telemedicine platform would also be subject to the prevailing **personal data protection rule**. Business actors need to consider gaining patients' consent for the use of their medical data along with the general/informed consent if this is intended.
3. Doctors and dentists who provide medical treatment through telemedicine services must provide a **medical record** for every patient and archive it at the healthcare facility in accordance with the prevailing laws and regulations. The medical record may be in written or electronic form and may be provided to patients in the form of a transcript but the original one must be kept at the healthcare facility where the doctors and dentists are registered.
4. Doctors and dentists may **provide a diagnosis (through telemedicine) and subject the patient to supporting medical examination procedures** in the form of:
 1. laboratory
 2. radio image
 3. therapy
 4. drugs prescription (except narcotics and psychotropic) and/or medical devices
 5. explanation letter (*surat sakit*)
5. Telemedicine services that can be provided by doctors and dentists are subject to some limitations. Below are the actions that **doctors and dentists are prohibited to do in providing healthcare services through telemedicine**:
 1. conduct teleconsultation with patients without any involvement of a healthcare facility²
 2. provide misleading, non-ethical and inadequate information and/or explanation to patients and/or their families
 3. diagnose and treat patients outside of their competence
 4. require patients to conduct unnecessary additional medical assessments
 5. conduct immoral, intimidating and reprehensible actions against the patients
 6. conduct invasive actions through teleconsultation
 7. impose additional costs outside costs settled by the healthcare facility
 8. provide a letter of healthiness (*surat keterangan sehat*)
6. Doctors and dentists who provide medical treatment through telemedicine services may receive payment as determined by the healthcare facility they are registered to in accordance with the prevailing laws and regulations. This implies that any payment for the telemedicine service (through a payment platform or otherwise) must observe the internal rule of the healthcare facility where the doctors or dentists are registered, and **direct payment to the doctors and dentists providing the services might not be possible**.

Healthcare Services Act

ABOUT HEALTHCARE SERVICES ACT (HCSA)

- » **Broadened Regulatory Scope**
- » **Introduction to Licensable Healthcare Services, Mode of Service Deliveries and Specified Services**
- » **Refined Roles and Responsibilities of Key Personnel**
- » **De-linking Inspections from Licence Renewals**
- » **Licence Fees under HCSA**
- » **Who needs to hold a HCSA Licence**

New care models for patients have emerged, and healthcare services are increasingly delivered through different modes, such as conveyance, mobile and online channels. This necessitates a shift towards a more flexible approach in the regulation of Singapore's healthcare system. Under the Private Hospitals and Medical Clinics Act (PHMCA) and regulations, healthcare providers are licensed based on different types of premises (e.g., medical clinic, nursing home, hospital, clinical & x-ray laboratory) while under HCSA, healthcare providers will be licensed based on the healthcare services provided.

HCSA better safeguards patient safety and well-being in the changing healthcare environment, while enabling the development of new and innovative healthcare services. It also strengthens governance and regulatory clarity for better provision and continuity of care to patients.

<https://www.moh.gov.sg/hcsa/about-hcsa#Broadened-Scope>

KEY CHANGES FROM PHMCA TO HCSA

A. Broadened Regulatory Scope

Under HCSA, the regulatory scope will be broadened to potentially include **a wider scope of healthcare services, allied health services, nursing services, traditional medicine, and complementary and alternative medicine (Figure 1)**. Services that do not provide direct patient care, such as Beauty and wellness services, *are not included* in the scope of HCSA, as such services do not involve the assessment, diagnosis, prevention, alleviation or treatment of a medical condition or disorder.

MOH will adopt a **risk-based regulatory approach in determining which services are licensable under HCSA**. While allied health services, nursing services, traditional medicine and complementary and alternative medicine are potentially within the scope of HCSA, MOH *will not* be licensing these services for the moment. The practice of professionals such as physiotherapists and Traditional Chinese Medicine practitioners will continue to be regulated through the existing Professional Acts.

The Healthcare Services Act (HCSA) will replace the current Private Hospitals and Medical Clinics Act (PHMCA) in phases. Phases 1 and 2 were implemented on 3 January 2022 and 26 June 2023 respectively. Phase 3 will be implemented by December 2023

Healthcare Services Act

B. Introduction to Licensable Healthcare Services, Mode of Service Deliveries and Specified Services

I. Licensable Healthcare Services under HCSA

Under HCSA, healthcare providers will need to apply for approval to hold licences for the **licensable healthcare services (LHS)** they provide, as well as the appropriate **modes of service delivery (MOSD)** applicable for the LHS. This is a change from the PHMCA where providers are licensed based only on physical premises.

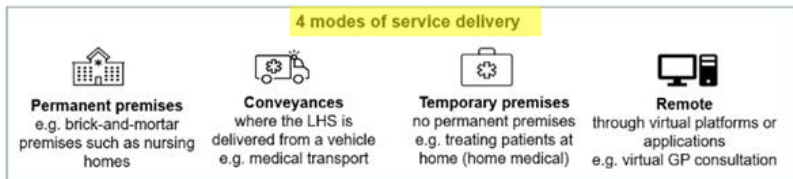
The introduction of **Specified Services (SSes)** for each LHS is another change from PHMCA to HCSA. Licensees will also need approval from the Ministry of Health prior to offering these SSes. SSes generally involve complex or higher risk procedures provided in a LHS and have distinct requirements for patient safety. The approval regime for SSes builds on the approval process that was in place for special care services in medical clinics, and specialised procedures and services in private hospitals set out under the PHMC regulations.

More information on the MOSDs and SSes are provided below. Click [here](#) to see which HCSA Phase(s) your service(s) are in.

II. Modes of Service Delivery

To cater for new and emerging models of care that are no-longer premises based (e.g. home care, telemedicine), there will be **4 modes of service delivery (MOSDs)** under HCSA (**Figure 2**). MOH will define the allowable MOSDs for each LHS. Licensees **must** seek MOH's approval for the MOSDs used to deliver each LHS.

Figure 2: Modes of Service Delivery under HCSA

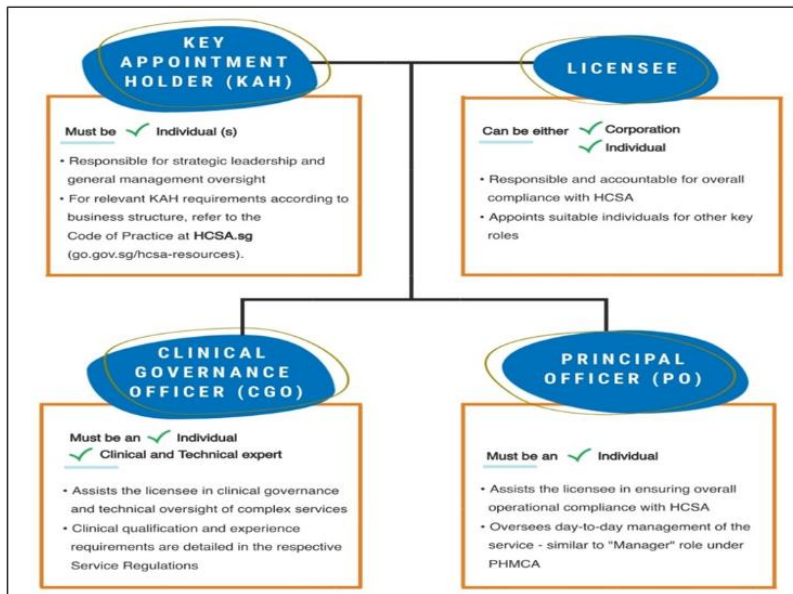


C. Refined Roles and Responsibilities of Key Personnel

Governance and oversight of healthcare services will be strengthened with the formalisation of the **Key Appointment Holder (KAH)**, the **Principal Officer (PO)** and the appointment of a **Clinical Governance Officer (CGO)** for selected services, in addition to the **licensee**. Please refer to **Figure 3** for a summary of these roles.

Suitability requirements of the various roles are promulgated in Regulations, Licence Conditions and a Code of Practice. Click [here](#) for more details on the roles and responsibilities of these key personnel.

Figure 3: Summary of Key Roles under HCSA



A quick regulatory guide to telehealth services in Japan

Telehealth services involve complex regulatory considerations and challenges in Japan. While not intended to be a comprehensive guide, this article highlights some regulatory issues that non-physician service providers need to be aware of.

By [Aiko Yamada and Nobuki Wada, K&L Gates](#) | June 09, 2022 | 03:22 AM

Responsibilities of Service Provider

Responsibilities of telemedicine platform providers

As discussed above, only licensed physicians are qualified and permitted to engage in telemedicine as a "medical practice". The MHLW Telemedicine Guidelines require physicians engaging in telemedicine to comply with obligations provided therein, and also require **a provider of a telemedicine platform to establish and provide a secure platform and to fulfil accountability about the platform** (i.e., potential security risks) **for the physicians**.

In order to be secured as the MHLW Telemedicine Guidelines require, the platform shall have certain **security systems** which include, without limitation, access management through multifactor authentication, establishment of measures to prevent an unauthorized access and an improper transfer or reuse of a domain and to **verify personal identification**, **access log monitoring** and management, regular **software update alert function**, and communication encoding with a **reliable server certification**.

Responsibilities of telecommunications service providers

The Telecommunications Business Act imposes certain obligations and responsibilities on a telecommunications service provider. If the service of a telehealth service provider is considered telecommunications business, it shall file (or register, as the case may be) as discussed above and comply with stipulated obligations and responsibilities, a summary of which is as follows:

General obligations: no censorship; protection of the privacy of communications; fair and equal access by users; appropriate management of emergency situations.

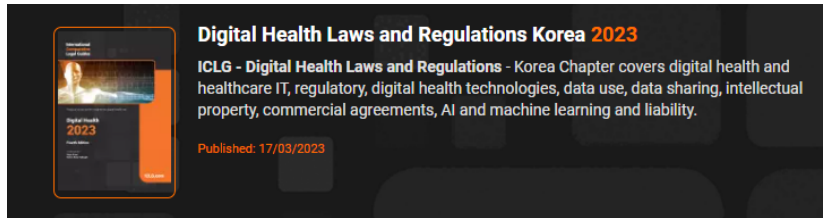
Obligations to protect users: notification and documentation of the terms of use; notification of the cessation or discontinuance of service; appropriate management of complaints; prohibitions of certain behaviours disadvantageous to users; appropriate monitoring of contractors.

Reporting and inspection: prompt reporting of the suspension of service; the divulgence of the privacy of communications or any other critical troubles or accidents in communication; obedience of the government order of business improvement; obedience of the government order of reporting or access and inspection.

As for recent developments, a bill to amend the Telecommunications Business Act will likely be enacted soon. The bill generally aims to: (a) **secure stable broadband infrastructure**; (b) secure a **safe and reliable telecommunications network**; and (c) establish a **fair and competitive environment**. The foregoing (b) might involve a telehealth service provider, depending on the situation including the type and scale of service, since it requires certain service providers to appropriately manage certain information of users by establishing governance mechanisms and notification to users of the transfer of their information to any third party, unless statutorily exempted. A telehealth service provider who finds a possibility of providing a telecommunications service in Japan might have to keep following the progress in the discussion.

A black and white photograph showing several people in business attire gathered around a table, looking at and pointing to various charts and documents. The image is partially obscured by a large red circular graphic on the right side of the slide.

สิ่งที่หวังว่าจะไม่เกิดขึ้นสำหรับการแพทย์ทางไกล
ในอนาคตสำหรับประเทศไทย?



3. Digital Health Technologies

3.1 What are the core issues that apply to the following digital health technologies?

- **Telemedicine/Virtual Care:** Under the Medical Service Act, **telemedicine is allowed only between physicians:** (a) physicians can receive support for patient treatment and diagnosis from other physicians via telecommunication devices; but (b) "physician-to-patient" telecommunication is not permitted. However, the government **permitted "physician-to-patient" telemedicine on a temporary basis, so as to cope with the COVID-19 pandemic, by amending the Infectious Disease Control and Prevention Act in December 2020.** Since then, the **government has attempted to convert such temporary telemedicine scheme to a permanent one by amending the Medical Service Act, and continues to discuss with medical societies the details of telemedicine** (e.g., permitted disease or treatment, prerequisite conditions, national health insurance reimbursement, etc.); however, no notable consensus has yet been reached by the government and medical societies.

- **Robotics:** Robotic surgery equipment is widely used in Korea; however, as far as digital health is concerned, no significant issues are being discussed.
- **Wearables:** Many wearable devices are introduced in Korea as wellness products or medical device products, the latter of which will require the MFDS's market approval. As medical services can be provided only by healthcare professionals under the Medical Service Act, wearable devices are not allowed to provide information or services that can be deemed medical services as defined by relevant Supreme Court precedents. In this regard, the MOHW provides guidelines on the health information that can be provided through wearable devices.
- **Virtual Assistants (e.g. Alexa):** Virtual assistants draw relatively less attention in Korea; however, similar issues as in the case of wearable devices can apply.
- **Mobile Apps:** Mobile apps are one of the hottest areas in Korea, and the MFDS has established the Safety Management Guideline for Medical Mobile Apps in this regard.
- **Software as a Medical Device:** Notable SaMD products are introduced in Korea, and it is understood that significant investments continue to be made for SaMD development. According to the MFDS data, 49 SaMD products were newly approved in 2022 while only six products were approved in 2018. The MFDS has displayed a keen interest in continuing to issue regulatory guidelines and policies for SaMD.
- **Clinical Decision Support Software:** The majority of SaMD products approved by the MFDS may be classified as clinical decision support software. According to the MFDS data, 31 SaMD products were classified as clinical decision support software among 49 SaMD products that were approved in 2022.
- **Artificial Intelligence/Machine Learning Powered Digital Health Solutions:** Artificial Intelligence/Machine Learning Powered Digital Health Solutions can also require the MFDS's market approval if the product is deemed a medical device. According to the MFDS guideline, artificial intelligence-based medical imaging software that can be deemed a medical device are as follows: (i) those that analyse medical data to diagnose, predict, monitor or treat diseases; and (ii) those that analyse medical data to provide clinical information necessary for the diagnosis or treatment of a patient.
- **IoT (Internet of Things) and Connected Devices:** There are no specific guidelines regulating IoT and connected devices in the digital health field. However, given the nature of these technologies, more emphasis may be imposed on the protection of personal data.
- **3D Printing/Bioprinting:** The government classifies 3D printing/bioprinting as one of innovative medical devices under the Act on Nurturing the Medical Devices Industry and Supporting Innovative Medical Devices.
- **Digital Therapeutics:** Among the 49 SaMD products approved in Korea, 17 products are digital therapeutics. The diseases for which these digital therapeutics are intended to be used include ADHD, mild cognitive impairment, developmental disorder, alleviation of addiction as well as insomnia.
- **Natural Language Processing:** No particular development has been made from a regulatory or governmental policy perspective.

Digital Health Laws and Regulations Korea 2023

ICLG - Digital Health Laws and Regulations - Korea Chapter covers digital health and healthcare IT, regulatory, digital health technologies, data use, data sharing, intellectual property, commercial agreements, AI and machine learning and liability.

Published: 17/03/2023

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Following its establishment in 1977, Lee & Ko has steadily grown to become one of Korea's leading full-service law firms. Headquartered in Seoul, South Korea, the firm has strategically positioned itself in the heart of the country's bustling business and legal centre, allowing it to effectively serve clients both domestically and internationally.

Lee & Ko maintains specialised practice groups and teams in a variety of areas. These include but are not limited to, corporate and finance law, intellectual property, litigation and dispute resolution, antitrust and competition, employment and labour and tax.

The firm's professionals comprise top qualified Korean and foreign lawyers and highly qualified accountants, former high-ranking government officials as advisors on regulatory matters, patent agents and academics. Lee & Ko serves a diverse range of clients, including domestic and international corporations, government agencies, financial institutions and individuals. The firm's client base spans industries such as finance, technology, manufacturing, energy, healthcare, and entertainment.

In the 1990s Lee & Ko was the first Korean law firm to establish specialised legal practice teams and acted as legal counsel to several major Korean corporations facing unprecedented financial and insolvency challenges during the Asian financial crisis of 1997.

Accepting its corporate and social responsibility, the firm actively encourages its attorneys and other professionals to utilise their expertise and knowledge to provide pro bono services to people in need. Lee & Ko and all members of the firm also regularly take part in charitable activities and work closely with numerous non-profit organisations.

10.4 What are the **key barrier(s) holding back widespread clinical adoption of digital health solutions in your jurisdiction?**

It is difficult for a digital health solution to replace traditional medical services under the Medical Service Act which requires that the medical service be provided by a **licensed healthcare professional at a medial institution**. Further, given the universal national insurance system in Korea, it would be necessary for a digital health solution to be eligible for the **national health insurance reimbursement** so as to be widely used by medical service providers.

10.5 What are the **key clinician certification bodies (e.g., American College of Radiology, etc.) in your jurisdiction that influence the clinical adoption of digital health solutions?**

No significant guidelines have been provided by major clinician certification bodies.

10.6 Are patients who utilise digital health solutions reimbursed by the government or private insurers in your jurisdiction? If so, does a digital health solution provider need to comply with any formal certification, registration or other requirements in order to be reimbursed?

With regard to private insurance, it depends on each insurance company's policies, and no significant general policy consensus has yet been established in the industry. However, as far as the national health insurance is concerned, the following processes are required: (i) the MFDS's product approval or certification under the Medical Devices Act; (ii) nHTA under the Medical Service Act if a new health technology is to be adopted; and (iii) review and determination of reimbursement eligibility under the National Health Insurance Act.

10.7 Describe any other issues not considered above that may be worthy of note, together with any trends or likely future developments that may be of interest.

The government has a firm view that the digital health sector is one of key industries that will lead national growth in coming decades.

[Editorial] Telemedicine dispute

Policymakers must upgrade remote medical services via pilot program

By Korea Herald

Published : 2023-06-01 05:30:46

Telemedicine services were provided to 14.2 million patients over the three-year period from 2020 through April this year in connection with treatment of the novel coronavirus, according to the Health and Welfare Ministry. But it was only temporarily available.

A growing number of experts and patients who appreciate the advantages of remote medical services have called for the government to make them part of regular medical treatment.

However, this is no easy task. At this moment, telemedicine lacks legal grounds now that the pandemic is receding and full-fledged remote medical services are strongly opposed by certain medical groups and doctors concerned about the possibility that their expertise and interests may be compromised.

Against this backdrop, the government has decided to launch a telemedicine pilot program from June, though such services will be strictly limited to second-visit patients, some patients who are unable to visit clinics or those who have treatment records that meet certain conditions.

Under the pilot program, patients who visit clinics at least once within a year can use the contactless medical services. Exceptions for the second-visit-only rule are applied to those who suffer from infectious diseases or live on remote islands, as well as the elderly who cannot visit clinics, among others.

It is regrettable that the pilot service comes with a severely restricted scope and such conditions. Given that 99 percent of remote medical services during the pandemic period involved first-visit patients, it hampers the key advantage of telemedicine, especially for those with light illnesses that require only a single consultation and prescription.

The Health Ministry and the Korea Medical Association struck a deal in February to attach such strict conditions, one of which is to ban the establishment of new medical institutions specializing in remote medical services.

There is no doubt that physical contact between doctors and patients is far superior to remote medical services in many ways. Doctors can better check the detailed condition of patients and offer more accurate diagnoses, not to mention offering treatment or additional examinations including blood tests at hospitals and clinics as necessary.

But health authorities and doctors have to face the reality of Korea's quickly aging population as demand for medical services is soaring across the nation.

Those living in metropolitan areas are in a relatively better condition since a number of big hospitals and midsize clinics offer regular and emergency medical services. But remote areas critically lack local hospitals, doctors, nurses and related facilities. Traveling from rural areas for hours to big cities for a brief consultation with a doctor is often a big challenge for those who do not qualify for the exceptional conditions.



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