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Transforming Healthcare in Indonesia: Key Changes in the New Health Law

Formulated in response to Indonesia's array of diverse healthcare-related legislation, Law No. 17 of 2023 on Health ("**New Health Law**") aims to integrate and simplify similar provisions for ease of public understanding. At the same time, this law also introduces significant amendments to the Indonesian healthcare sector.

Below are the laws that have been replaced by the New Health Law:

- 1. Law No. 419 of 1949 on Dangerous Drugs Ordinances ("Dangerous Drugs Ordinance Law");
- 2. Law No. 4 of 1984 on Infectious Disease Outbreaks ("Infection Disease Epidemics Law");
- 3. Law No. 29 of 2004 on Medical Practices ("Medical Practices Law");
- 4. Law No. 36 of 2009 on Health ("Old Health Law");
- 5. Law No. 44 of 2009 on Hospitals ("Hospitals Law");
- 6. Law No. 20 of 2013 on Medical Education ("Medical Education Law");
- 7. Law No. 18 of 2014 on Mental Health ("Mental Health Law");
- 8. Law No. 36 of 2014 on Health Workers ("Health Workers Law");
- 9. Law No. 38 of 2014 on Nurseries ("Nursery Law");
- 10. Law No. 6 of 2018 on Health Quarantines ("Health Quarantines Law"); and
- 11. Law No. 4 of 2019 on Midwifery ("Midwifery Law").

This Advisory summarizes some key changes made by the recently enacted New Health Law.

A. Simplified Licensing Procedures for Healthcare Workers

The revised procedures for healthcare workers include: (i) lifetime validity of Letters of Registration (*Surat Tanda Registrasi* or "STR"); (ii) updated prerequisites for obtaining a license to practice (*Surat Izin Praktik* or "SIP"); and (iii) updated requirements for professional overseas graduates and foreign medical professionals seeking to practice in Indonesia.

i. Lifetime validity of STRs

To practice medicine in Indonesia, healthcare workers must possess an STR. The STR serves as written proof of registration and is issued by an independent regulatory body known as a Council, acting on behalf of the Minister of Health. Under the New Health Law, healthcare workers can only obtain an STR if they hold an educational certificate for their respective healthcare profession and a certificate of professional competence. This is different from the requirements under the Health Workers Law, which included the necessity of a physical and mental health certificate, a written statement that he/she has taken a professional oath, and a written commitment to uphold professional ethics. These are no longer needed to obtain an STR.

In addition, under the Health Workers Law, an STR was only valid for 5 years, after which it had to be renewed. Now, under Article 260 (4) of the New Health Law, an STR is valid for life.

ii. SIP

An SIP is defined as a written proof issued by the respective municipality or regencylevel government, permitting a health worker to practice medicine. The New Health Law requires certain health workers to hold a valid STR and a designated medical practice location for them to obtain an SIP. This is slightly different from the previous requirement, which also necessitated a recommendation from a relevant professional organization to obtain an SIP. SIPs will continue to be valid if the medical practice location remains the same as that stated in the SIP.

iii. Requirements for Overseas Graduates and Foreign Professionals to Practice in Indonesia

The New Health Law opens opportunities for both Indonesian citizens who are overseas graduates and foreign healthcare professionals (both doctors and healthcare professionals) to practice in Indonesia. Both Indonesian citizens who are overseas graduates and foreign professionals who intends on practicing in Indonesia must first pass a competency evaluation conducted by the Indonesian government. Competency evaluations consist of an evaluation of the administrative requirements and one of the required practical skills. However, an exemption from this evaluation requirement can be obtained under the following conditions:

Parties	Exemption to pass competency evaluations
Professional Overseas Graduates (Article 243 of the New Health Law)	 The overseas graduate is formally recognized and has been practicing medicine for at least 2 years overseas; or
	 he/she is a qualified expert in a certain medical field as proved by a relevant certificate.
Foreign Professionals That Are Overseas Graduates	 The overseas graduate is recognized and has practiced as a specialist or subspecialist doctor

(Article 250 of the New Health Law)		or healthcare professional with a certain level of competence for at least 5 years; or
	0	he/she is a qualified expert in a certain medical field, as proved by a relevant certificate, and he/she has been practicing for at least 5 years.

Specifically for foreign doctors and healthcare professionals who are overseas graduates, only specialist and sub-specialist doctors and healthcare workers with a certain level of competence can practice in Indonesia. In this case, they require both an STR and an SIP and must also pass the competency evaluation elaborated above. These professionals with the certain level of competence may only practice in healthcare service facilities in Indonesia under the following circumstances:

- a) a request has been submitted by a certain healthcare service facility.
- b) a transfer of technology and knowledge must be involved;
- c) the practice duration is limited to 2 years, extendable once for up to an additional 2 years.

B. <u>Rights of Data Owners in the Healthcare Information System</u>

The healthcare information system was previously regulated under Government Regulation No. 46 of 2014 on the Healthcare Information System ("**GR 46/2014**"). It is defined as the overall system which processes information, provides indicators and procedures, and consists of equipment, technology and human resources that are interconnected and managed systematically to take action or make decisions beneficial for healthcare development.

The New Health Law introduces several provisions on healthcare information systems. Operators of healthcare information systems now include the Central Government, Regional Governments, healthcare service facilities, and individual members of the public or certain groups. The New Health Law also mandates obtaining approval from the Central Government for any transfer of data and information managed by a healthcare information system operator to outside Indonesia.

In line with the requirement under Law No. 27 of 2002 on Personal Data Protection, healthcare information system operators must guarantee the security of data and information related to the health of every individual. Therefore, the consent of data owners is required to process their data and information. Under Article 351 of the New Health Law, data owners have the following rights:

- i. to receive information about the purpose for which their health information is being collected;
- ii. to access and revise the data and information collected through the healthcare information system operator;

- iii. to ask the healthcare information system operator to transfer their data to another healthcare information system;
- iv. to ask the healthcare information system operator to delete inaccurate on their behalf; and
- v. to exercise the rights of personal data owners under the current regulations on personal data protection.

Healthcare information system operators must also notify data owners of any breaches in the protection of their medical data or information.

C. Recognition of Telemedicine and Telehealth Services

The New Health Law recognizes the provision of telemedicine and telehealth services. Telemedicine services are defined as the facilitation of clinical services through telecommunications and digital communication technology. Meanwhile, telehealth services are defined as the delivery and facilitation of health services, including public health, health information, and self-service, also through telecommunications and digital communication technology. Telemedicine and telehealth services can be provided independently by health service facilities or through cooperation with registered electronic system providers. In any case, telehealth and telemedicine services must be provided by health workers who hold a proper license to practice. These types of services will be regulated further under a forthcoming implementing regulation.

D. <u>Healthcare Products</u>

Several articles in the New Health Law directly impact stakeholders in the healthcare product industry. These articles introduce the following specific requirements in the areas listed below:

i. <u>Pharmaceutical supplies, medical devices and household health products</u>

- (i) The manufacture, storage, promotion and distribution of pharmaceutical supplies must meet the applicable safety, efficacy and quality standards.
- (ii) The requirement to hold a business license to distribute pharmaceutical supplies, medical supplies and household health products does not apply to mobile traditional herbal medicine (*jamu gendong*) businesses, traditional herbal medicine (*jamu*) concoction businesses or production facilities for special drugs.
- (iii) Natural medicines, health supplements, quasi-medicines and certain cosmetics used for pharmaceutical supplies must meet the applicable quality standards and requirements.
- (iv) Only pharmacists may engage in pharmaceutical activities, but other medical professionals may do so with certain limitations.
- ii. Food and Beverages

Producers, manufacturers and distributors of food and beverages must meet the safety, quality, and nutrition standards that apply under the relevant regulations. For certain products, they must also obtain certification as halal products.

iii. Addictive Substances

Tobacco is the product that the New Health Law specifically acknowledges as an addictive substance. This includes products such as cigarettes, cigars, leaf cigarettes, chopped tobacco, liquid and solid forms of tobacco, and other related items. Unlike under the Old Health Law, "other addictive substances" are no longer referred to.

E. Government-Led Incentives

Article 331 of the New Health Law outlines the Central Government's commitment to provide incentives to pharmaceutical supply and medical device industries. These incentives target businesses engaged in research, development and innovation for these industries within the country, as well as the use of domestic raw materials. The incentives are both fiscal and non-fiscal.

F. Medical Liability

To protect healthcare workers, the Ministry of Health ("**MOH**") has adjusted the provisions on medical liability under the New Health Law. The sanctions for various crimes are modified, as shown in the table below:

Crime	Legal Basis (New	Criminal Sanction
	Health Law)	
Abortion by mothers without permitted reasons ¹	Article 427	4 years in prison
Abortion with the consent of the mother ²	Article 428 (1) (a)	5 years in prison
Abortion without the consent of the mother ³	Article 428 (1) (b)	12 years in prison
Abortion with the consent of the mother causing the death of the mother ⁴	Article 428 (2)	8 years in prison
Abortion without the consent of the mother causing the death of the mother ⁵	Article 428 (3)	15 years in prison
Abortion by a healthcare worker (unless the abortion is necessary because of an	Article 429	Added with one-third of the relevant criminal sanction
emergency or the mother is a rape victim)		Additional sanctions include the revocation of: a. a public position; and/or

¹ See: Article 60 of the New Health Law

² See: *Ibid*

³ See: *Ibid*

⁴ See: Ibid

⁵ See: Ibid

		b. membership of a certain profession.
Disruption of a breastfeeding program by mothers ⁶	Article 430	Imprisonment for up to 1 year or a fine of up to Rp50 million
Human blood trading 7	Article 431	Imprisonment for up to 3 years or a fine of up to Rp200 million
Organ or cell transplant commercialization ⁸	Article 432 (1)	Imprisonment for up to 5 years or a fine of up to Rp500 million
Organ or cell trading ⁹	Article 432 (2)	Imprisonment for up to 7 years or a fine of up to Rp2 billion
Performing reconstructive plastic surgery that is not in line with local norms or is intended to change the identity of an individual ¹⁰	Article 433	Imprisonment for up to 10 years or a fine of up to Rp2 billion
Violating or instructing an individual to violate the human rights of individuals with mental disabilities ¹¹	Article 434	Imprisonment for up to 2 years and 6 months or a fine of up to Rp10 million
Producing or distributing pharmaceutical supplies or medical equipment that does not satisfy safety, efficacy, and quality standards ¹²	Article 435	Imprisonment for up to 12 years or a fine of up to Rp5 billion
Engaging in pharmaceutical activities without any qualifications or authorization ¹³	Article 436 (1)	A fine of up to Rp200 million
Engaging in pharmaceutical activities without any qualifications or authorization, when using potent drugs	Article 436 (2)	Imprisonment for up to 5 years and a fine of up to Rp500 million
Producing, importing or distributing cigarettes without health warning images or written health disclaimers ¹⁴	Article 437	Imprisonment for up to 5 years or a fine of up to Rp500 million

⁶ See: *Ibid*, Article 42

- ⁷ See: *Ibid*, Article 119
- ⁸ See: *Ibid*, Article 124 (3)
- ⁹ See: *Ibid*, Article 124 (3)

- ¹⁰ See: *Ibid*, Article 124 (3)
 ¹⁰ See: *Ibid*, Article 137 (2)
 ¹¹ See: *Ibid*, Article 76 (2)
 ¹² See: *Ibid*, Article 138 (2) and (3)
 ¹³ See: *Ibid*, Article 145 (1)
 ¹⁴ See: *Ibid*, Article 150

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Engaging in smoking in non- smoking areas ¹⁵		A fine of up to Rp50 million
Failing to provide first aid to patients in a healthcare facility during emergencies ¹⁶	Article 438 (1)	Imprisonment for up to 2 years or a fine of up to Rp200 million
Failing to provide first aid to patients in a healthcare facility during emergencies, resulting in a patient's disability or death	Article 438 (2)	Imprisonment for up to 10 years or a fine of up to Rp2 billion
Practicing medicine without being a medical professional or healthcare worker or holding an SIP	Article 439	Imprisonment for up to 5 years or a fine of up to Rp500 million
Acting negligently as a medical professional or healthcare worker, resulting in severe injury in a patient	Article 440 (1)	Imprisonment for up to 3 years or a fine of up to Rp250 million
Acting negligently as a medical professional or healthcare worker, resulting in a patient's death	Article 440 (2)	Imprisonment for up to 5 years or a fine of up to Rp500 million
Using a title that falsely implies being a medical professional or healthcare worker with an STR or SIP ¹⁷	Article 441 (1)	Imprisonment for up to 5 years or a fine of up to Rp500 million
Using equipment, methods, or conduct that falsely implies being a medical professional or healthcare worker with an STR or SIP ¹⁸	Article 441 (2)	Imprisonment for up to 5 years or a fine of up to Rp500 million
Employing medical professionals or healthcare workers who lack an SIP ¹⁹	Article 442	Imprisonment for up to 5 years or a fine of up to Rp500 million
As a ship's captain, airplane pilot or driver, intentionally dropping off or picking up people or goods without prior approval from the MOH, with the potential to spread diseases that may lead to an epidemic ²⁰	Article 443	Imprisonment for up to 10 years or a fine of up to Rp2 billion

- ¹⁵ See: *Ibid*, Article 151
- ¹³ See: *Ibid*, Article 151
 ¹⁶ See: *Ibid*, Articles 174 and 275 (1)
 ¹⁷ See: *Ibid*, Article 312 (a)
 ¹⁸ See: *Ibid*, Article 312 (b)
 ¹⁹ See: *Ibid*, Article 312 (C)
 ²⁰ See: *Ibid*, Article 363 (3)

Falsifying documents related to a health quarantine by inputting false information ²¹	Article 444	Imprisonment for up to 5 years or a fine of up to Rp500 million
Engaging in activities that spread materials containing a source of a disease with the potential to cause an outbreak ²²	Article 445	Imprisonment for up to 12 years or a fine of up to Rp5 billion
Not complying with efforts to counter an epidemic or deliberately preventing efforts to counter an epidemic ²³	Article 446	A fine of up to Rp500 million

Furthermore, in cases where a company is found guilty of an offense under Articles 428, 430–435, 437, 442, 444, 445, or 446 of the New Health Law, criminal sanctions will apply to the company, as well as the responsible personnel, instructor, person in charge, or beneficial owner. In addition to imprisonment and a fine, the following additional fines may be imposed on the company:

- i. Rp2 billion for crimes punishable with imprisonment for less than 7 years.
- ii. Rp5 billion for crimes punishable with imprisonment from 7–15 years.
- iii. Rp50 billion for crimes punishable with life imprisonment or imprisonment for up to 20 years.

Furthermore, a company convicted under Articles 428, 430–435, 437, 442, 444, 445, or 446, may face the following additional sanctions:

- i. An order to pay damages;
- ii. Revocation of certain licenses; or
- iii. Closure of a part or all of the business or an order to cease certain business activities.

G. Implementing Regulations

Following the issuance of the New Health Law, Circular of the Minister of Health of the Republic of Indonesia No. K.02.01/MENKES/1911/2023 of 2023 on the Organization of Registration and Licensing of Medical Workers and Health Workers After the Issuance of Law Number 17 of 2023 on Health has also been issued. In short, this circular is intended to be a reference for authorized institutions involved in granting STR and SIP to medical and health workers in Indonesia, encompassing the aspects elaborated in section (A) of this advice above. As of November 2023, further implementing regulations have not been issued.

²¹ See: *Ibid*, Article 366

²² See: *Ibid*, Article 399

²³ See: *Ibid*, Article 400

H. Closing

Improving public health has always been one of Indonesia's top priorities. Expectations are high that this New Health Law will expedite much-needed improvements. However, we are still awaiting the issuance of the implementing regulations, which is anticipated to occur within 1 year. For companies in Indonesia's booming healthcare sector, reliable legal advice is essential to ensure compliance and a thorough understanding of the new law.

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