

Background of the Act: Enactment of Personal Data Protection Legislation in 2003 and Its Amendment in 2015

History of PDP Legislation and Next Generation Act

May 30, 2003	Personal Data Protection (hereinafter as PDP) Legislation Enacted.	
	◆Personal Data Protection Legislation includes the following:	
	●Personal Data Protection Act	
	●Administrative Agencies Personal Data Protection Act	
	●Independent Administrative Corporation Personal Data Protection Act	
April 1, 2005	Full Implimentation of Personal Data Protection Legislation.	
Sept. 9, 2015	Personal Data Protection Act Amended.	
May 12, 2017	Next-Generation Medical Infrastructure Act Enacted.	
May 11, 2018	Next-Generation Medical Infrastructure Act Coming into Force.	

3

Summaries of the PDP Act

- Specification of the purpose of use in the processing of personal data is required.
- When personal data is collected, notification to the data subject or publication of the purpose of use is required.
- (Without the consent of the subject) The use of personal data beyond the specified purpose of use is prohibited unless otherwise authorized by law.
- (Without the consent of the Subject) The sharing of personal data with the third party is prohibited unless otherwise authorized by law.
- The disclosure or correction request by the data subject must be adequately accommodated.

4

2015 Amendment to the PDP Act

- Clarification of the Difinitions of Personal Data.
- Utilization of personal data under adequate control and security.
- Enhanced protection of personal data: ensuring traceability of data sharing.
- Creation of the Personal Data Protection Committee as the regulating body.
- Accommodating global processing of personal data.
- Other necessary amendments.

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2015 Amendment to the PDP Act

- Clarification of the Difinitions of Personal Data.
- The amendment created a new category of "personal data requiring special care."[§ 2 (3)]
- "Personal Data Requiring Special Care" is defined personal data that contains the data subject's race, creed, social status, medical history, criminal record, fact of having suffered injury by criminal acts, or other descriptions prescribed by cabinet order as requiring special care in processing lest the unfair discrimination, prejudice or other disadvantage will occur on the part of the data subject.

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2015 Amendment to the PDP Act

- In health and medical area, the Cabinet Order implementing the 2015 Amendment added the following three categories of description to "medical history" set out in the act itself. [§ 2]
 - The presence of mental or physical disability.
 - The results of health checkup or other medical tests.
 - That health consultation, medical care or prescription filling was provided to improve the subject's mental and physical condition.
- ➡ All medical and health data is, in effect, characterized as "personal data requiring special care."

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Amended PDP Act § 17 (2)

- Collecting "personal data requiring special care" is allowed only where the advance consent of the subject is obtained, except in the following cases.
 - (i) cases allowed by legislation.
 - (ii) cases in which there is a need to protect a human life, body or property, and when it is difficult to obtain a subject's consent.
 - (iii) cases in which there is a special need to enhance public health or promote fostering healthy children, and when it is difficult to obtain the subject's consent.
 - (iv) ***.
 - (v) ***.

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Amended PDP Act § 23 (1)

- Sharing with third parties of personal data is allowed only where the advance consent of the subject is obtained, except in the following cases.
 - (i) cases allowed by legislation.
 - (ii) cases in which there is a need to protect a human life, body or property, and when it is difficult to obtain a subject's consent.
 - (iii) cases in which there is a special need to enhance public health or promote fostering healthy children, and when it is difficult to obtain the subject's consent.
 - (iv) ***.

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Amended PDP Act § 2 (9)

- "Anonymized data" means the data relating to an individual that has been created by processing the personal data to make it (1) neither individually identifiable (2) nor restorable to any personal data.

10

Summary of the Next-Generation Medical Infrastructure Act [hereinafter referred to "the Act"]

Definition of Entities and Agent

Medical Data Processing Entity [Processing Entity]	Entity using medical data database (e.g. hospital, clinic, school and employer)
Accredited Medical Data Anonymizing Agent [Anonymizing Agent]	Governmentally accredited private entity that creates anonymized medical data stored in systematically organized database by collating and anonymizing medical data to promote R&D in the medical field
Anonymized Medical Database User Entity [User Entity]	Entity that utilize database of anonymized medical data (e.g. pharmaceutical company, research institution, and administrative body)

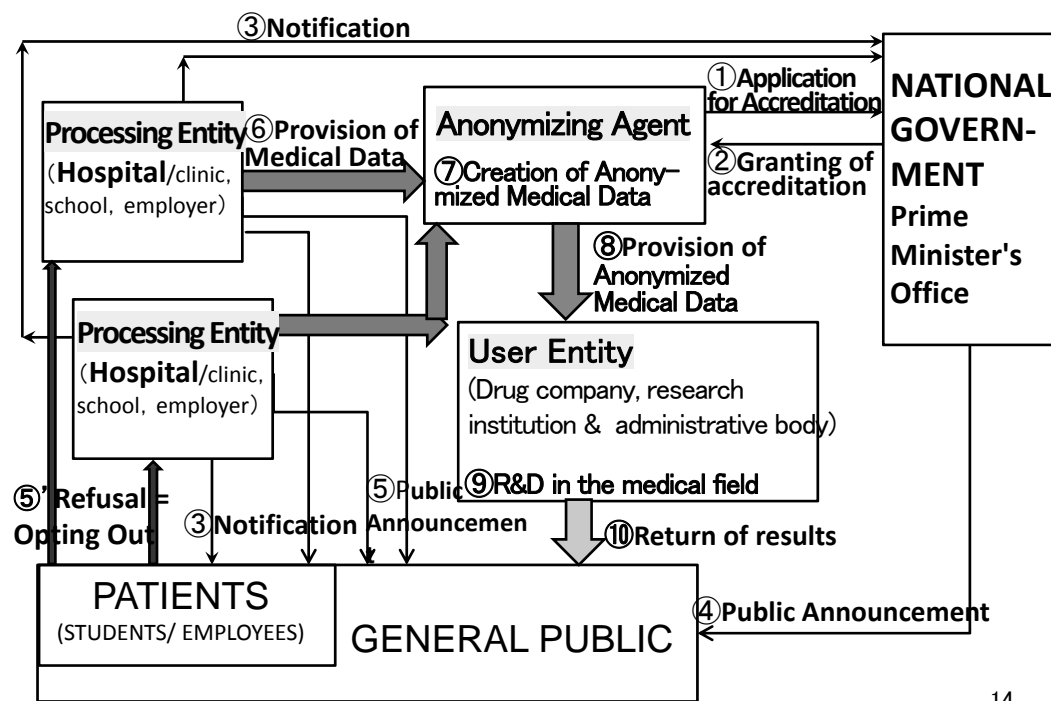
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Definition of Medical Data under the Act

- "Medical data" is defined under the Act to mean the data relating to a [either living or dead] individual that contains the following descriptions about mental and physical condition of the individual.
 - (i) the medical history;
 - (ii) the presence of mental or physical disability;
 - (iii) the results of health checkup or other medical tests;
 - (iv) that health consultation, medical care or prescription filling was provided to improve the subject's mental and physical condition.

13



14

Prime Minister's Office

The Act provides that Prime Minister, Minister of Education and Science, Minister of Health, Labor and Welfare and Minister of Economy, Trade and Industry are the ministers in charge of the Act.

In fact, the Office of Health Care Strategies at the Prime Minister's Office seems to be the leading authority supervising the administration of the Act.

When a prospective Anonymizing Agent would like to start its operation under the Act, it must first apply for and obtain the accreditation from the supervising authority.[①②] The accreditation will be granted only when the applicant shows that:

- (1) it meets the standard set by the regulation for judging the ability to properly create and provide anonymized medical data by collecting and collating data for medical R&D.
- (2) appropriate security measures are in place to prevent the leakage, loss or damage of data.
- (3) it has the ability to properly administer the security measures prescribed in (2).

[So far, no entity has been granted the accreditation.]

15

Medical Data Processing Entities (e.g. Hospitals)

Medical Data Processing Entities such as hospitals and clinics may provide Accredited Medical Data Anonymizing Agent with medical data of the patients for collation, linkage and anonymization, provided that:

1. They notify the patients and the supervising authority of their intention to provide the Anonymizing Agent with their patients' medical data. [③]
2. The patients do not express their refusal (opting-out). [⑤']
3. They make public announcement by using appropriate means (such as Internet website) regarding:
 - (1) that they participate in the data providing scheme;
 - (2) contents of the medical data to be provided;
 - (3) method for providing data;
 - (4) that the provision of identified medical data will be stopped upon receiving the request by the individual or her/his surviving family members;
 - (5) method for accepting the request. [⑤]

16

Prime Minister's Office

When the Processing Entity submits to the supervising authority the notification of its intention to provide the Anonymizing Agent with its patients' medical data and other information concerning the provision of data [③], the authority must publish the contents of the notification by the appropriate way including the use of the Internet. [④]

When the authority make the publication, the Processing Entity must also publish its intention and other information concerning the provision of patients' data to the Anonymizing Agent. [⑤]

17

Patients

Patients of medical institutions are given the leaflet letting them to know that, unless they express their objection, their identified medical data will be shared with the Anonymizing Agent that will collate and anonymize data for the use by User Entities such as pharmaceutical company, research institution or government agency. [③]

Even after the patient's data is provided to the Anonymizing Agent, the patient can request to delete her/his data or the data derived from it. The Anonymizing Agent is required to delete the data as far as practicable.

18

Accredited Medical Data Anonymizing Agent

The entity must obtain government accreditation to conduct the anonymization of medical data under the Act. [①②]

The Anonymizing Agent will create anonymized medical data by collating, linking [data of the same individual from different sources] and anonymizing the identified medical data provided by the Processing Entities such as Hospitals. [⑦]

The Anonymizing Agent will provide anonymized medical data for a fee to User Entities such as pharmaceutical companies, research institutions and government agencies for R&D. [⑧⑨]

19

Anonymized Medical Database User Entity

The Anonymizing Agent provides a User Entity with the anonymized medical data, provided that the review committee of the Anonymizing Agent determine that the following requirements are satisfied:

- (1) The purpose of the use is suitable for adequate medical R&D;
- (2) The modes of use is scientifically valid;
- (3) When the result of the R&D is provided to the general public, the manner of the publication of the results of R&D is properly devised not to cause any disadvantages to other people of the community or group than the data subject or her/his surviving families;
- (4) The account and administration of the revenue from R&D is adequate. [Guidelines about the Act, Chap. of Accredited Agent 10-11]

20

Advantages obtained by Using the Act's scheme

【No express consent necessary: Adoption of the Patient Friendly Opting-Out System】

The Act creates the scheme that allows the use of anonymized medical data dispensing with the necessity of the patient's express consent, as long as the patient does not object to the use after given the information about the transfer and anonymization under it.

(Under the amended PDP Act, the patient's express consent must be obtained for the collection and transfer of medical data [as data requiring special care] unless authorized by its exemption clauses).

21

Advantages obtained by Using the Act's scheme

【Data Integration possible】

Under the Act, medical data from multiple processing entities (e.g. hospitals, clinics, employers or schools) can be integrated by linking the data by name, address, and other identifiers.

22

Additional Advantages Suggested by the Government

【Responsibility for the Creation of Anonymized Data】

Under the Act, the Anonymizing Agent will bear, and the Processing Entity (e.g. hospitals) will be relieved of, all of the responsibilities concerning the creation of anonymized medical data.

【Security of Medical Data】

As the Anonymizing Agent is accredited as meeting the high standard of technical and management capabilities, the security of anonymizing process is, in a sense, guaranteed by the Government.

23

Additional Advantages Suggested by the Government

【No Ethical Review Necessary】

Ethical review is not necessary for

- (1) Providing by a Processing entity (e.g., hospital) to an Anonymizing Agent with identified medical data;
- (2) Receiving by an Anonymizing Agent of identified medical data, and providing a User Entity with created anonymized medical data;
- (3) Utilizing by a User Entity of anonymized medical data for medical R&D.

However, a User Entity, in order to obtain anonymized medical data, must submit itself to the review of the committee established by the Anonymizing Agent.

24

Will the scheme under the Act work?

Under the Act, Processing Entities such as hospitals and clinics are free to participate in the scheme created by the Act.

The patient is also free to opt out from the scheme.

The success of the scheme seems dependent on how the Processing Entities are positive about participating in it, which will be affected by the patient 's perception of the scheme or entities participating in it.

Whether the patients value affirmatively the hospital's participation in it or they feel concern about the security of their medical data processed by the participating entities and Agents.

These questions are yet to be answered.

25