

Outline of the Bill to Partially Amend the Act on Anonymized Medical Data That Are Meant to Contribute to Research and Development in the Medical Field

1. Creation of a Structure Related to the Use of Pseudonymized Medical Data

In addition to the preparation and provision of anonymized medical data under the current Act, **as a new activity, pseudonymized medical data will be prepared, and a structure for its use will be created.**

Pseudonymized Medical Data : it is information that has been processed in a manner such that unless it is collated with other information, it is impossible to identify a specific individual. Although it is necessary to remove information such as the name and ID from personal information, unlike anonymized medical data, it is not necessary to remove idiosyncratic descriptions and rare diseases, etc.

1. Certification of Businesses Preparing Pseudonymized Medical Data

- The State will **certify businesses that prepare and provide pseudonymized medical data** after receiving the submission of medical information from a medical institution based on the notification by individuals (certified businesses preparing pseudonymized medical data).

2. Certification of Businesses Using Pseudonymized Medical Data

- Certified businesses preparing pseudonymized medical data are **limited to those users who have been certified by the State** based on safety management and other standards, and **these businesses are allowed to provide pseudonymized medical data** (businesses certified to use pseudonymized medical data).
- Businesses certified to use pseudonymized medical data **are not allowed to re-identify pseudonymized medical data or provide it to a third party** (Exceptions may be made for submission to organizations such as PMDA* and for joint use between businesses certified to use pseudonymized medical data). * Pharmaceuticals and Medical Devices Agency, (Incorporated Administrative Agency), the Japanese regulatory agency that conducts approval examinations for pharmaceuticals and medical devices

3. Use of Pseudonymized Medical Data to Assist in Approval of Pharmaceuticals

- In order to apply for approval of pharmaceuticals, businesses certified to use pseudonymized medical data **may submit pseudonymized medical data to PMDA and other agencies.**
- The businesses certified to use pseudonymized medical data will be **enabled to re-identify** pseudonymized medical data in order to **respond to the investigation** of businesses certified to use pseudonymized medical data conducted by PMDA based on the law related to the quality, efficacy and safety of pharmaceuticals and medical devices (Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices)

2. Consolidation With Public Databases Such as NDB

Anonymized medical data based on this Act and access to public databases such as the NDB* and nursing care databases in a state where consolidated analysis is possible can be provided to researchers.

* A database that manages information on specific medical examinations, specific health guidance, and receipt information, based on the Act on Assurance of Medical Care for Elderly People

3. Cooperation Concerning the Policy to Advance the Use of Medical Data

Regarding businesses handling medical data, there are provisions encouraging them to make efforts to cooperate with national policy through **the submission of medical data to certified businesses.**

Effective Date: with a partial exception, the date provided for by Cabinet Order not exceeding one year from the date of promulgation

医療分野の研究開発に資するための匿名加工医療情報に関する法律の一部を改正する法律案の概要

1. 仮名加工医療情報の利活用に係る仕組みの創設

現行法による匿名加工医療情報の作成・提供に加え、**新たに「仮名加工医療情報」を作成し、利用に供する仕組みを創設**する。

（**仮名加工医療情報**：他の情報と照合しない限り、個人を特定できないよう加工した情報。個人情報から氏名やID等の削除が必要だが、**匿名加工医療情報とは異なり、特異な値や希少疾患名等の削除等は不要。**）

1. 仮名加工医療情報の作成事業者の認定

- 医療機関等から本人通知に基づき医療情報の提供を受けて**仮名加工医療情報を作成・提供する事業者を国が認定**する。（認定仮名加工医療情報作成事業者）

2. 仮名加工医療情報の利活用者の認定

- 認定仮名加工医療情報作成事業者は、安全管理等の基準に基づき**国が認定した利活用者に限り、仮名加工医療情報を提供**することができる。（認定仮名加工医療情報利用事業者）
- 認定仮名加工医療情報利用事業者は、**仮名加工医療情報の再識別及び第三者提供を禁止**（PMDA※等への提出や、認定仮名加工医療情報利用事業者間の共同利用は例外的に可能）。※医薬品の承認審査等の業務を行う(独)医薬品医療機器総合機構

3. 薬事承認に資するための仮名加工医療情報の利活用

- 薬事承認申請のため、認定仮名加工医療情報利用事業者から**PMDA等に対する仮名加工医療情報の提供を可能**とする。
- PMDAが、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律（薬機法）に基づいて認定仮名加工医療情報作成事業者に対して行う**調査に対し、同事業者による再識別を可能とすることで回答**できるようにする。

2. NDB等の公的データベースとの連結

本法に基づく匿名加工医療情報と、NDB※や介護DB等の公的データベースを連結解析できる状態で研究者等に提供できることとする。

※高齢者医療確保法に基づき、国民の特定健診や特定保健指導情報、レセプト情報を管理するデータベース

3. 医療情報の利活用推進に関する施策への協力

医療情報取扱事業者に関し、**認定事業者への医療情報提供等**により国の施策への協力に努めることを規定。

施行日：一部を除き、公布の日から1年以内で政令で定める日