

Japanese Health Policy

September 2026



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1. Background

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1.1

Background | Japan's Population Structure and Disease Profile

Japan's Population

Japan's total population is approximately 123.8 million. As of 2024, around 37.9 per cent of the national population is concentrated in Tokyo, Kanagawa, Osaka, Aichi, and Saitama Prefectures. Among these, Tokyo has the largest population, accounting for roughly 11.4 per cent of the total.¹

Increased Prevalence of Low Fertility and Rapid Population Ageing^{2,3}

Japan's healthcare system is currently confronted with profound demographic challenges posed by an ageing population and a persistently low birth rate. During the post-war period, the baby boom generation (born between 1947 and 1949) contributed to substantial rise in births in tandem with rapid economic growth. As a result, until the 1960s, the proportion of young people remained comparatively high and Japan's ageing rate was lower than international standards.

However, population ageing subsequently advanced at an exceptional pace. The proportion of older adults surpassed 7 per cent in 1970 and reached over 14 per cent by 1994. Although the second baby boom (born between 1971 and 1974) occurred when women of the baby boom generation reached their most fertile years, the absence of a third baby boom is widely regarded as a major factor contributing to Japan's sustained low fertility.

Population ageing has exerted a considerable impact on Japan's social security system. In 2015, the baby boom generation entered the early elderly age group (65–74 years), and by 2025 the number of older adults had reached approximately 36 million.⁴ Whereas earlier concerns about ageing centered on its rapid progression; however, since 2015 the sheer volume of the elderly population has emerged as the more pressing issue.

Particularly noteworthy is that 2025 marked the year in which the baby boom cohort turned 75, signaling a transition towards a “super-ageing society” characterized by a growing proportion of the very old. Together with rising expenditure on healthcare and long-term care, this demographic shift was referred to as the “2025 Problem.”⁵ It was projected that one in four citizens would be aged 75 or above, and that the proportion of all older adults, including the early elderly, would exceed 30 per cent. In reality, as of September 2025 the ageing rate reached 29.4 per cent, the highest ever recorded,

¹ Statistics Bureau of Japan, Ministry of Internal Affairs and Communications. *Population Estimates*. <https://www.stat.go.jp/data/jinsui/2024np/index.html>

² Cabinet Office. *White Paper on the Ageing Society 2025 (FY2025 Edition, Full Version)*. https://www8.cao.go.jp/kourei/whitepaper/w-2025/zenbun/pdf/1s1s_01.pdf

³ Ministry of Health, Labour and Welfare. Overview of the 2024 (Reiwa 6) Vital Statistics Monthly Report: Annual Total (Preliminary Figures). <https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai24/dl/gaikyouR6.pdf>

⁴ Ministry of Internal Affairs and Communications. Older Persons in Japan: Statistical Overview. <https://www.stat.go.jp/data/topics/pdf/topics146.pdf>

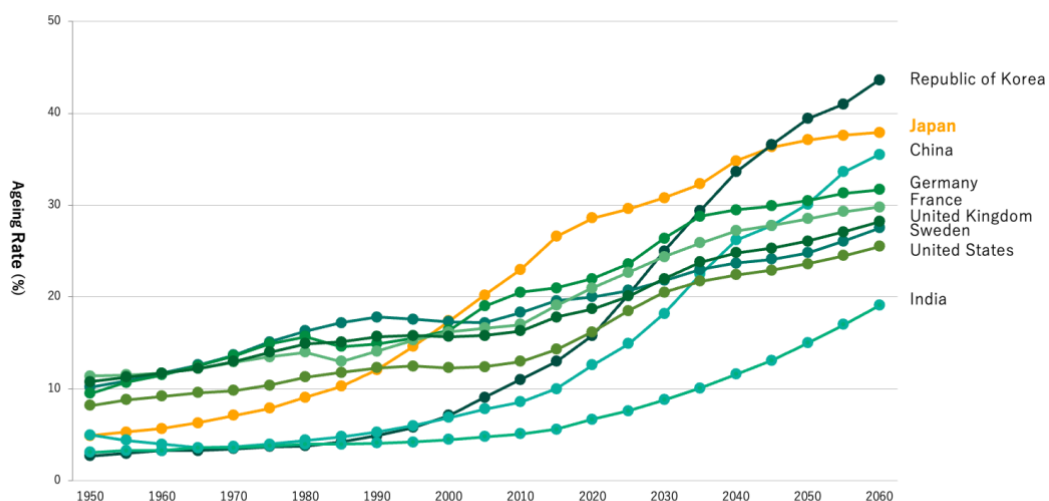
⁵ Imai, H. (2016). “What Is the ‘2025 Problem’? Various Aspects of the Challenges Facing Public Health.” *Journal of Health and Medical Sciences*, Vol. 65, No. 1, pp. 2–8. <https://www.niph.go.jp/journal/data/65-1/201665010002.pdf>

and it is expected to continue rising.⁶

Furthermore, by 2040 the second baby boom cohort will reach age 65 and above, and the elderly population is anticipated to peak. While the growth in the number of older adults is expected to decrease, the decline in the working-age population will accelerate, intensifying labor shortages, an issue often conceptualized as the “2040 Problem”; in contrast to the 2025 demographic turning point. Despite these pressures, projections suggest that the level of social security expenditure in 2040 will remain lower than that of France or Sweden in 2023.⁷

The figure below further illustrates that Japan’s ageing is progressing at an unparalleled speed relative to other countries. At the same time, similar demographic shifts are anticipated in China and South Korea, positioning Japan as a potential model for navigating the transition to a super-ageing society at the global level.

Figure 1-1-1 Trends in Ageing Rates by Country



Note 1 : 2020 Data up to that year are actual figures; 2025 data from that year onward are projections.
Note 2 : The ageing rate is defined as the proportion of the population aged 65 and over.

Source: Cabinet Office. “White Paper on the Ageing Society, FY6 (Full Version).”
https://www8.cao.go.jp/kourei/whitepaper/w-2024/html/zenbun/s1_1_2.html

At the same time, Japan is experiencing a marked decline in the number of births. Annual births peaked at approximately 2.7 million in 1949, fell below 2 million in 1975, and have continued to decline gradually, thereafter with intermittent fluctuations. In 2016, the number of births fell below 1 million. Although the total fertility rate had shown an upward trend from 2006, it declined in 2014, rose again in 2015, and has since continued to fall. As of 2024, it stands at a historic low of 1.15, highlighting the severity of the demographic crisis.⁸

In recent years, the decline has further accelerated, and the period up to the 2030s, when the young population is projected to contract sharply, has been described as a critical turning point. If the

⁶ Ministry of Internal Affairs and Communications. Older Persons in Japan: Statistical Overview.

<https://www.stat.go.jp/data/topics/pdf/topics146.pdf>

⁷ Ministry of Health, Labour and Welfare. Summary of the Social Security and Work Style Reform Headquarters with a View to 2040.

<https://www.mhlw.go.jp/content/12601000/001471353.pdf>

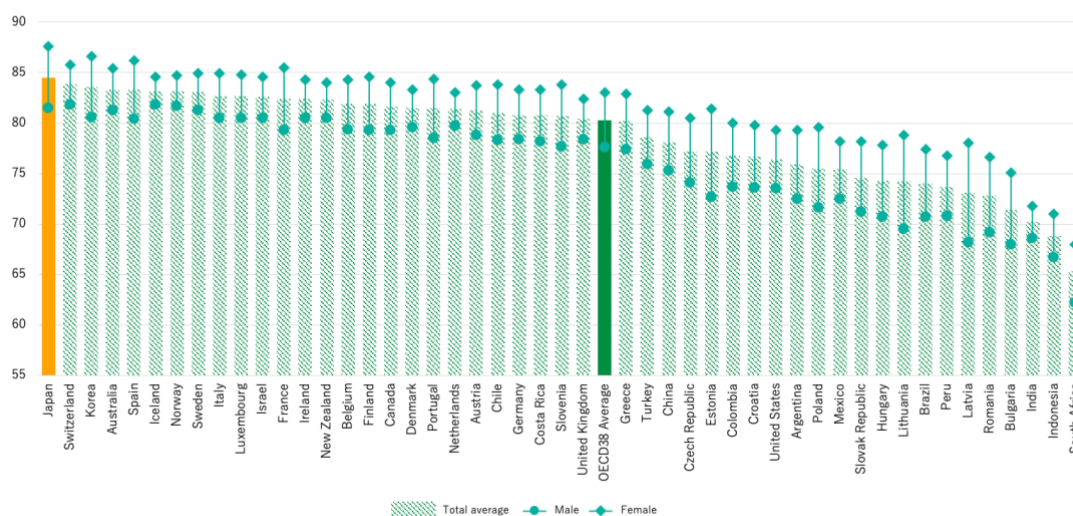
⁸ Ministry of Health, Labour and Welfare. Overview of the 2024 (Reiwa 6) Vital Statistics Monthly Report: Annual Total (Preliminary Figures). <https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai24/dl/gaikyouR6.pdf>

downward trend is not reversed by 2030, Japan is expected to face irreversible population decline.⁹

Life Expectancy, Healthy Life Expectancy, and Disease Trends

Japan's life expectancy remains among the highest in the world, at 87.14 years for women and 81.09 years for men. Japan also has a notably high healthy life expectancy (defined as years lived without limitations on daily activities due to health problems), which as of 2022 stands at 72.57 years for men and 75.45 years for women.¹⁰ As a result, Japan has a large population of older adults who remain in good health, with high levels of social participation and employment. A 2024 survey found that 35.6% of older adults were engaged in paid work.¹¹

Figure 1-1-2 Life Expectancy by Country (2021 — Life Expectancy at Birth)



Note 1 : Data for the United Kingdom are from 2020; data for Turkey are from 2019.

Source : OECD Health Statistics 2023, Eurostat 2023 for EU/EEA countries.

Next, we turn to the disease profile of the Japanese population. In Japan, a national Patient Survey is conducted every three years in order to capture the medical conditions and other health-related issues of all patients utilizing healthcare facilities. The graph below illustrates consultation rates by disease category.

For inpatient care, the most prevalent categories are mental and behavioral disorders and circulatory diseases. For outpatient care, the most frequent categories are diseases of the digestive system and factors influencing health status and contact with health services. These data highlight notable differences between inpatient and outpatient patterns of healthcare utilization.

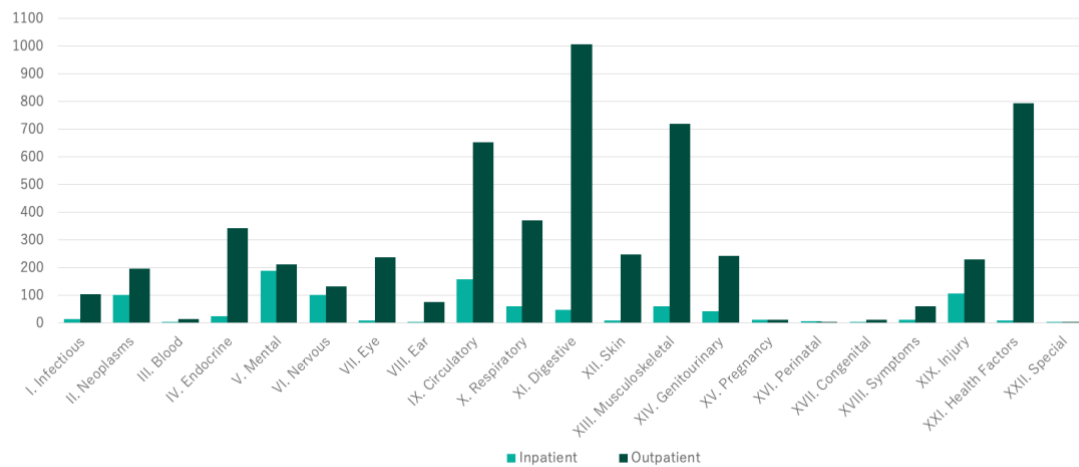
⁹ Children and Families Agency. Children's Future Strategy.

https://www.cfa.go.jp/assets/contents/node/basic_page/field_ref_resources/fb115de8-988b-40d4-8f67-b82321a39daf/b6cc7c9e/20231222_resources_kodomo-mirai_02.pdf

¹⁰ Cabinet Office. White Paper on the Ageing Society 2025 (FY2025 Edition, Full Version). https://www8.cao.go.jp/kourei/whitepaper/w-2025/zenbun/pdf/1s1s_01.pdf

¹¹ Cabinet Office. White Paper on the Ageing Society 2025 (FY2025 Edition, Full Version). https://www8.cao.go.jp/kourei/whitepaper/w-2025/zenbun/pdf/1s3s_01.pdf

Figure 1-1-3 Admission and Outpatient Treatment Rates by Type of Illness or Injury (2020)

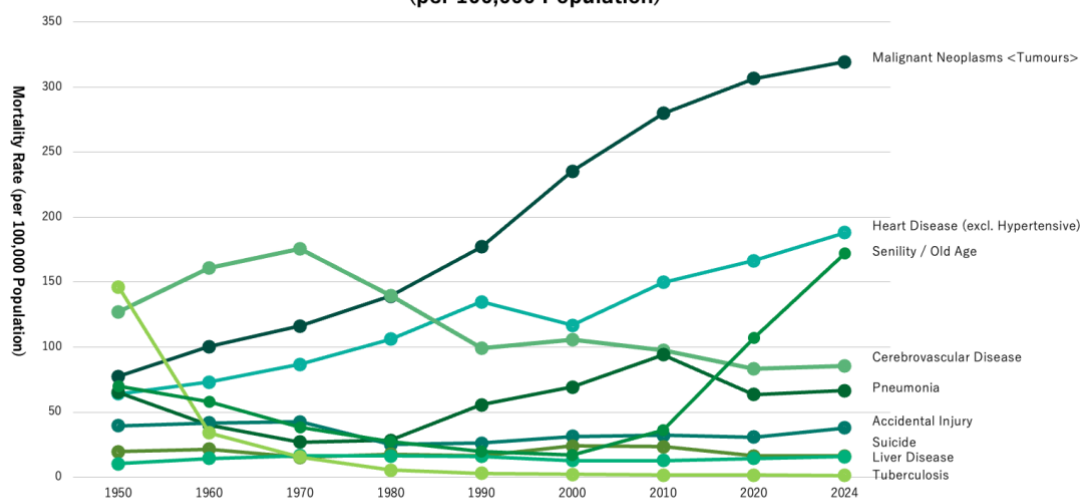


Note: The treatment rate is calculated as the estimated number of patients divided by the census population, multiplied by 100,000.

Source: Ministry of Health, Labour and Welfare, 'Overview of the 2020 Patient Survey'

Furthermore, the distribution of mortality by major causes has changed significantly across generations. Following the post-war period, deaths attributable to tuberculosis declined markedly, resulting in a fundamental shift in Japan's mortality structure from infectious diseases to the so-called non-communicable diseases (NCDs). Recent trends indicate that malignant neoplasms, heart disease, and senility constitute the three leading causes of death. In particular, with the rapid progression of population ageing in recent years, mortality from senility has been steadily increasing. While deaths due to cerebrovascular disease and pneumonia have shown a downward trend, mortality from suicide has remained persistently high compared with other countries.¹²

Figure 1-1-4 Annual Trends in Mortality Rate by Principal Cause of Death (per 100,000 Population)



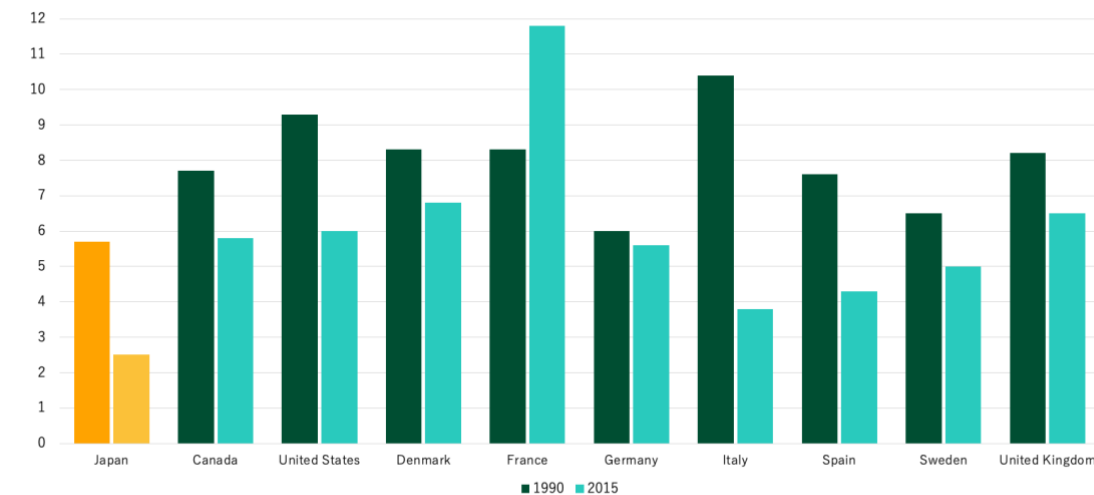
Note 1: 1994 Prior to that year, "Heart Disease (excl. Hypertensive)" is recorded as "Heart Disease."
Note 2: 1994 - 1995 Note 2: "Heart Disease (excl. Hypertensive)" for that year

Source: Ministry of Health, Labour and Welfare.
"Reiwa6年（2024）Annual Summary of Vital Statistics Monthly (Preliminary Figures)."
<https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai24/dl/gaikyouR6.pdf>

¹² Health and Welfare Statistics Association. Trends in National Health, Vol. 71, No. 9, 2024/2025.

Regarding perinatal mortality, which comprises stillbirths occurring from 22 weeks of gestation onwards and early neonatal deaths within the first week of life, the situation in Japan has shown continuous improvement since the post-war period, and the current rate remains low compared with that of other countries.¹³

Figure 1-1-5 International Comparison of Perinatal Mortality Rates



Note 1 : For international comparison, perinatal mortality uses the pre-revision definition (stillbirths from 28 weeks of gestation plus early neonatal deaths, per 1,000 live births).
 Note 2 : The 1990 figure for Germany refers to the former West Germany.

Source: Health, Labour and Welfare Statistics Association. (2024).
 Health and welfare statistics in Japan, Vol. 71, No. 9, 2024/2025 (Trends in national health)

1.2 Background | The Medical Insurance System

The Central Role of Public Health Insurance in Japanese Health Policy

The fundamental principles underpinning Japanese health policy are universal health insurance coverage and free access. In other words, all residents are enrolled in some form of public health insurance, and patients are free to choose medical institutions and the frequency of consultations. Both principles are sustained by the public health insurance system.

Since 1961, Japan has operated under a universal health insurance system, whereby all residents are required to be covered by a public medical insurance scheme. This feature distinguishes Japan's health insurance system from those of many other countries. Consequently, within the healthcare system, the role of public health insurance is of exceptionally high importance.

Japan's public health insurance system is broadly categorized into three schemes:

- **Employee Health Insurance (Employment-based Insurance):** Covers employees of companies and public-sector organizations under the age of 75 who are engaged in formal employment.
- **National Health Insurance:** Applies to individuals who are not covered by employee health insurance (including its dependents) and who are not enrolled in the Late-Stage Elderly Medical

¹³ Health and Welfare Statistics Association. Trends in National Health, Vol. 71, No. 9, 2024/2025.

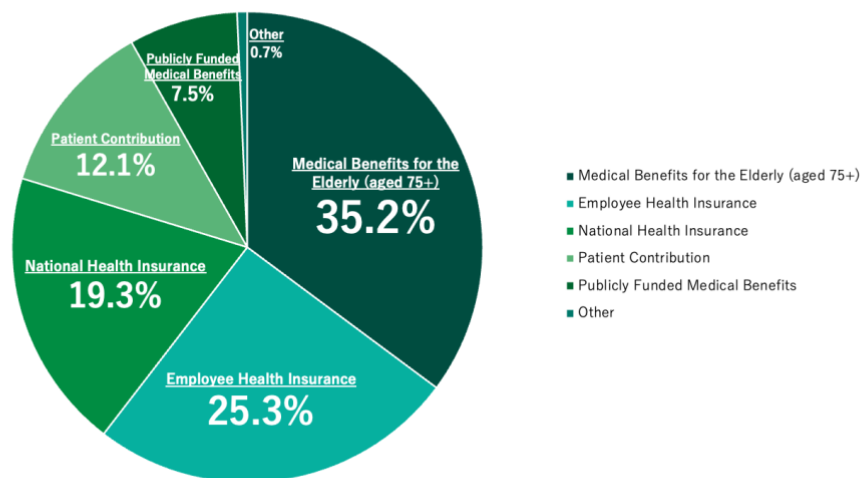
Care System, such as the self-employed and agricultural workers.

- Late-Stage Elderly Medical Care System: In principle, this scheme covers individuals aged 75 years and older.

Japan's national healthcare expenditure, an estimate of total treatment costs incurred at domestic medical institutions, is financed through a combination of public expenditure, health insurance benefits (employee health insurance, national health insurance, and the late-stage elderly medical care system), and out-of-pocket payments by patients. The breakdown is illustrated in the figure below.¹⁴ Approximately 80% of national healthcare expenditure is covered by the health insurance system, thereby indicating its substantial role.

Furthermore, publicly funded medical benefits are administered through mechanisms that largely align with those of the health insurance system. As a result, although medical assistance provided under the public assistance program, accounting for roughly half of publicly funded medical benefits, represents a major exception to the principle of universal health insurance, public medical insurance schemes remain central to health policy considerations. Medical services not covered by the public insurance system, such as fully self-funded private medical care, currently account for only 1.2% of total national healthcare expenditure.

Figure 1-2-1 Breakdown of National Healthcare Expenditure (2022)



Note 1: Patient co-payments include patient charges and compulsory motor liability insurance payments.
Note 2: Other includes medical costs under the Workers' Accident Compensation Insurance Act and other relevant legislation.

Source: Ministry of Health, Labour and Welfare. "Reiwa4(2022)
<https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/22/dl/data.pdf>

Another defining feature of Japan's healthcare system, alongside universal coverage, is unrestricted access to care. This means that all individuals are free to consult healthcare providers of their choice. Although access is an element of the healthcare provision framework, this freedom is underpinned by the public health insurance system. Seeing as most domestic healthcare providers are registered as authorized providers under the public insurance schemes, patients are able to receive necessary

¹⁴ Ministry of Health, Labour and Welfare. National Healthcare Expenditure by Insurance Scheme, FY2022.

services at a standard, regulated co-payment irrespective of which insurance scheme they are enrolled in.

Initiatives Beyond the Public Health-Insurance Framework

In addition to the structures described above, the Ministry of Health, Labour and Welfare pursues targeted measures for major disease categories and specific policy programs.¹⁵ The following summarizes the principal areas of those efforts.

	Relevant Legislation, Policies, and Current Context	Priority Issues and Development of the Healthcare Delivery System
Cancer	• Basic Act on Cancer Control • Basic Plan to Promote Cancer Control (national and prefectural levels) • Act on the Promotion of Cancer Registries, etc.	• 400 Designated Cancer Care Hospitals (as of April 2024) • 61 Regional Cancer Care Hospitals (as of April 2024) • Promotion of palliative care from the point of diagnosis • Promotion of cancer registration • Cancer Consultation and Support Centers
Cardiovascular diseases (stroke and heart disease)	• Basic Plan for Cardiovascular Disease Control • Proportion of individuals requiring long-term care due to cerebrovascular disease: 16.1% (2022)	• Specific Health Check-ups and Specific Health Guidance Programs • Development of emergency medical care systems • Hypertension control measures
Diabetes Mellitus	• Health Japan 21 (Third Term) • Health Promotion Act • Number of new patients initiating dialysis due to diabetic nephropathy: 14,430 (2022)	• Specific Health Check-ups and Specific Health Guidance • Municipal health promotion programmes • Program for the Prevention of Progression to Severe Diabetic Nephropathy
Psychiatric Disorders	• Mental Health and Welfare Act (inpatient medical care) • Dementia Basic Act and Basic Plan for the Promotion of Dementia Measures	• (Dementia-related measures) Early-stage Intensive Support Teams for Dementia, Dementia Medical Care Centers, Dementia Support Doctors, Adult Guardianship System, etc.

¹⁵ Health and Welfare Statistics Association (2024). Trends in National Health 2024/2025: Supplement to Journal of Health and Welfare Statistics, pp. 10–12.

	• Act on Comprehensive Support for Persons with Disabilities (outpatient psychiatric medical care) • Medical Treatment and Supervision Act for Persons Who Have Caused Serious Harm Due to Mental Incompetence • Act on Support for Persons with Developmental Disabilities • “Barrier-Free for Mental Health” Declaration	• Community-based Integrated Care System for Persons with Mental Disabilities • Mental Health and Welfare Centers: 69 facilities (as of December 2023) • Licensed Psychiatric Social Workers: 106,962 individuals (as of March 2024) • Holders of Mental Disability Health and Welfare Certificates: 1.345 million people (as of March 2023)
Intractable (Rare) Diseases	• Act on Medical Care for Patients with Intractable Diseases • Act on Comprehensive Support for Persons with Disabilities • Number of holders of Certificates for Specified Medical Expenses (Designated Intractable Diseases): 1.049 million (end of FY2022)	• 341 Designated Intractable Diseases (as of April 2024) • 81 Intractable Disease Care Coordination Core Hospitals (as of April 2023) • Intractable Disease Consultation and Support Centers
Infectious Diseases	• Infectious Diseases Control Act • Quarantine Act • Immunization Act • Basic Act on Hepatitis Measures / Basic Plan • Act on Special Measures for Pandemic Influenza and New Infectious Diseases	• Infectious Disease Surveillance System • Total number of quarantine stations: 111; fishing ports: 80; airports: 31 (as of April 2024) • HIV/AIDS treatment hub hospitals: 376 (as of 1 January 2024) • Vaccine Injury Compensation Program • Measures against COVID-19
Kidney Diseases	• Towards Further Promotion of Kidney Disease Countermeasures • Act on Comprehensive Support for Persons with Disabilities • Organ Transplant Act • Number of newly initiated dialysis patients: 39,683 (2022); number of patients receiving maintenance dialysis therapy: 347,474 (end of	• Development and provision of artificial kidney (dialysis) equipment • Chronic Kidney Disease (CKD) countermeasures • Development of the organ transplantation network • Program for the prevention of the progression of diabetic nephropathy

	2022)	
Emergency Medical Care	• Fire Service Act • Emergency Life-Saving Technician Act • Emergency dispatches: 7.23 million cases (2022)	• Primary emergency care: On-call physician systems in 557 districts; 550 holiday and night-time emergency clinics (as of 1 April 2022) • Secondary emergency care: Rotational hospital group system in 387 districts (as of 1 April 2022) • Tertiary emergency care: 304 Critical Care and Emergency Medical Centers (as of 1 April 2024) • Registered Emergency Life-Saving Technicians: 72,849 individuals (as of March 2024)
Disaster Medicine	• Disaster Countermeasures Basic Act • Ministry of Health, Labour and Welfare Disaster Prevention Operations Plan	• Designated disaster base hospitals: 776 (as of 1 April 2024) • Disaster Medical Assistance Teams (DMAT) • Disaster Psychiatric Assistance Teams (DPAT)
Healthcare in Remote and Underserved Areas	• Medically underserved areas: 557 areas; population 122,206 (as of 31 October 2022) • Guidelines for the Implementation of Measures for Healthcare in Remote Areas	• Core hospitals for remote-area healthcare: 348 facilities (as of 1 April 2023) • Remote-area clinics: 1,126 facilities (as of 1 April 2023)
Perinatal Care	• Maternal and Child Health Act • Low birthweight infants (under 2.5 kg): males 8.3%, females 10.6% (2022) • Preterm births (before 37 weeks' gestation): 43,327 births (5.6%) (2022) •	• Comprehensive Perinatal Medical Centers: 112 centers (as of 1 April 2024) • Regional Perinatal Medical Centers: 296 centers (as of 1 April 2024)
Paediatric	• Child Welfare Act	• Pediatric emergency care core hospitals:

Healthcare	• Maternal and Child Health Act • <i>Healthy Parents and Children 21</i> (Second Phase) • Leading causes of death by age group: • Ages 0 and 1–4: congenital malformations, deformations, and chromosomal abnormalities • Ages 5–9: malignant neoplasms (tumours) • Ages 10–14 and 15–19: suicide (2023)	36 (as of 1 April 2022) • Pediatric emergency and critical care centers: 18 (as of 1 April 2022) • Medical expense subsidy program for pediatric chronic diseases: 16 disease groups, 788 conditions covered (as of 1 November 2021) • Transitional care support centers • Pediatric medical telephone consultation service (#8000 program): 1.15 million calls (FY2022) • Child Guidance Centers: 234 centers (as of 1 April 2024)
Community Health and Medical Care	• Medical Care Act • Act on Securing Comprehensive Medical and Long-Term Care • Long-Term Care Insurance Act • Community Health Act	• Public health centers: 468; municipal health centers: 2,422 (as of April 2024) • Secondary medical service areas: 330 areas (as of April 2024) • Community General Support Centers: 5,431 facilities (as of April 2023) • Community-based Integrated Care System (regional medical care plans and hospital bed function reporting system) • Medical care plans, physician workforce securing plans, outpatient medical care plans
Home-Based Medical Care	• Medical Care Act • Act on Securing Comprehensive Medical and Long-Term Care • Long-Term Care Insurance Act • Community Health Act	• Community-based Integrated Care System • Home-based medical care collaboration hub hospitals for children and other populations • Expansion and enhancement of visiting nursing services
Dental and Oral Health	• Act on the Promotion of Dental and Oral Health • Health Japan (Second Phase / Third Phase)	• Promotion of the “8020 Campaign” • Dental health check-ups for children aged 18 months and 3 years • Periodontal disease screening (Health

	• Vision for Dental Health and Medical Care • Areas without dental clinics: 784 districts; population 188,647 (as of 31 October 2022)	• Promotion Program) • Oral function improvement for older adults (long-term care prevention) • Development of dental services for persons with disabilities and residents of remote areas
Suicide Prevention	• Basic Act on Suicide Prevention • General Principles of Suicide Prevention Policy • Prefectural and municipal suicide prevention plans • Number of suicides: 21,837 (2023) • Primary motive for suicide: health-related problems (12,403 cases in 2023)	• Training of gatekeeper • National mental health consultation hotline • SNS-based consultation services
Medical Safety Management	• Medical Care Act • Act on Securing Comprehensive Medical and Long-Term Care • Medical accident reports received: 3,099 cases; in-hospital investigation reports: 2,613 cases (October 2015 – March 2024)	• Medical Accident Investigation and Support Centre • Medical Safety Support Centers: 395 facilities (FY2023) • Infection control within medical institutions • Promotion of team-based medical care

In 2013, with the objectives of achieving world-leading medical technologies and services, extending healthy life expectancy, and fostering pharmaceuticals and medical devices as strategic industries to underpin Japan's economic revitalization, the Office for Healthcare and Medical Strategy was established within the Cabinet Secretariat. At the time, responsibilities in the health and medical field were dispersed across multiple ministries and agencies, creating a need for a central coordinating body with a command function under the Cabinet Secretariat. Subsequently, this body was renamed the Headquarters for Healthcare and Medical Strategy Promotion.

In 2014, the Act on Promotion of Healthcare and Medical Strategy was enacted, and in the same year the Healthcare and Medical Strategy was formulated pursuant to this legislation. The strategy set out two core pillars: (i) the provision of medical care utilizing technologies of the highest global standard, and (ii) contribution to economic growth. Since then, a wide range of cross-ministerial policies have been advanced beyond traditional administrative boundaries.

Another prominent example of a cross-sectoral, multi-ministerial approach is the Comprehensive Strategy for the Promotion of Dementia Policies (the "New Orange Plan"). This strategy was formulated

in 2015 in response to the increasing number of people living with dementia alongside population ageing, with the aim of creating a society in which the wishes of people with dementia are respected and they are able to continue living in familiar communities in a manner consistent with their own values and preferences.¹⁶ Distinct from previous dementia policies, the strategy attracted attention for its emphasis on the perspectives of people with dementia and their families, as well as for being jointly issued by twelve ministries and agencies, led by the Ministry of Health, Labour and Welfare, thereby incorporating a broad range of perspectives beyond welfare alone.

From 2019 onwards, the Dementia Policy Promotion Outline was newly established, placing particular emphasis on the principles of “coexistence” and “prevention”. Concretely, initiatives have included the development of systems for early detection and early response to dementia, as well as the strengthening of community-based support frameworks in collaboration with local governments.¹⁷ Building on these developments, the Basic Act on Dementia was enacted in 2023, under which the national government and local authorities are required to formulate plans and actively engage in the implementation of dementia-related policies.

1.3 Background | History of Public Health Insurance

Understanding the historical development of the public health insurance system is essential for grasping the current structure of Japan’s healthcare system. Broadly speaking, Japan’s public health insurance consists of three distinct schemes: employment-based insurance (Employees’ Health Insurance), community-based insurance (National Health Insurance), and an age-based scheme (the Medical Care System for the Elderly Aged 75 and over). In addition, medical assistance under the Public Assistance system exists, which is administered in a manner analogous to public health insurance (see Section 1.2).

Together, these three public health insurance schemes and the Public Assistance system form the foundation of one of the world’s largest health insurance systems, currently covering virtually the entire Japanese population as well as long-term residents in Japan (amounting to more than 127 million people). The existence of multiple schemes and multiple insurers reflects the historical process of repeated institutional reforms that have taken place since the enactment of the Health Insurance Act in 1922.

¹⁶ Ministry of Health, Labour and Welfare; Cabinet Secretariat; Cabinet Office; National Police Agency; Financial Services Agency; Consumer Affairs Agency; Ministry of Internal Affairs and Communications; Ministry of Justice; Ministry of Education, Culture, Sports, Science and Technology; Ministry of Agriculture, Forestry and Fisheries; Ministry of Economy, Trade and Industry; Ministry of Land, Infrastructure, Transport and Tourism. Comprehensive Strategy for the Promotion of Dementia Policies (New Orange Plan) (Overview). https://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/nop1-2_3.pdf

¹⁷ Ministry of Health, Labour and Welfare. Outline for the Promotion of Dementia Policies (Summary). <https://www.mhlw.go.jp/content/000519053.pdf>

The Emergence of Social Insurance: The Origins of Public Health Insurance

The wave of the Industrial Revolution that began in the United Kingdom in the late eighteenth and nineteenth centuries eventually reached Japan. In the latter half of the nineteenth century, Japan's industrial revolution gained momentum when government-owned factories were transferred to private ownership. At that time, the textile industry formed the core of modern industry, leading to a large influx of women and child laborers from rural areas into urban centers. These workers were often forced to work under extremely poor conditions, and many were sent back to their home villages due to illnesses such as tuberculosis.

In response to these circumstances, social movements emerged and calls for labor protection legislation intensified. However, these efforts were repeatedly thwarted by strong opposition from employers. Eventually, in 1911, the Factory Act was enacted to protect factory workers, although its provisions reflected numerous compromises and its enforcement was postponed until 1916. Nevertheless, the Act stipulated employers' responsibilities to provide assistance in cases of work-related injury or death, and may be regarded as the embryonic form of health insurance in Japan.

Establishment of the Health Insurance Act

The First World War, centered largely in Europe, led to rapid expansion of Japan's heavy and chemical industries, resulting in a marked increase in the number of adult male industrial workers. However, the post-war period was characterized by economic recession, mass unemployment, and an intensification of labor movements influenced in part by the Russian Revolution. Under these conditions, the government and political parties were compelled to pay greater attention to the status of workers.

The government therefore sought to ease class conflict by tolerating more moderate labor movements while simultaneously repressing more radical ones. As part of this strategy, in 1922 the Health Insurance Act was enacted with the objective of protecting workers. This legislation constitutes the direct predecessor of today's employment-based health insurance system.

At the time, however, the social security framework was still underdeveloped, with social insurance being established prior to the creation of a comprehensive public assistance system. Consequently, extensive coordination was required prior to implementation, particularly with regards to the system of healthcare provision. Medical associations, wary of the widespread provision of low-cost medical services, sought to assume responsibility for delivering care under the Health Insurance Act. As a result, negotiations between the government and medical associations, particularly over medical fee schedules, became routine.

Implementation of the system was further delayed by the Great Kantō Earthquake of 1923, and it was not until 1927 that the Health Insurance Act was finally enforced. Even then, the system faced unstable operation in its early years, as the economy struggled under the financial crisis of 1927 followed by the global Great Depression of 1929.

Experience of Fascism: The First Achievement of Universal Health Insurance

Japan's economy is often said to have recovered relatively quickly from the Great Depression. Two major factors contributed to this recovery: the expansionary fiscal policies implemented by Korekiyo Takahashi, and economic stimulus driven by military demand, as exemplified by the 1931 Manchurian Incident. Combined with the rise of fascism, these developments heightened awareness of the need for health policies aimed at strengthening national capacity and promoting a healthy, militarily fit population. As a result, public health insurance schemes were further expanded. Following the Marco Polo Bridge Incident in 1937, which triggered full-scale war between Japan and China, this momentum accelerated significantly.

First, the administration of health insurance, which had previously been unstable, was placed on a more sustainable footing as a result of economic growth. The collapse in raw silk prices during the Depression led to the decline of the textile industry, which was replaced by heavy industry as the backbone of the economy in support of military production. This structural shift increased the proportion of adult male policyholders within the health insurance system and, in combination with favorable economic conditions, substantially improved the financial position of health insurance funds. Consequently, the Health Insurance Act was amended in 1934, expanding eligibility. Further legislative measures in 1939 extended coverage to seafarers, white-collar workers, and the families of workers. It was during this period that community-based insurance schemes emerged. These were originally conceived as countermeasures to rural impoverishment, where economic recovery from the Depression had lagged. Layoffs of migrant workers and declining silk prices severely affected farm household incomes, while a sharp fall in rice prices following a bumper harvest in 1930, compounded by poor harvests the following year, further exacerbated rural economic hardship. The Social Affairs Bureau of the Ministry of Home Affairs began examining the establishment of an insurance system covering the general population outside the employed workforce as a means of improving health and nutritional conditions in rural areas. At the same time, rural poverty was increasingly perceived as a critical issue by the Army, which depended heavily on rural areas as sources of military manpower. This led to growing involvement by the military, and, bolstered by its political influence, the National Health Insurance Act was enacted in 1938. At that time, however, enrolment in National Health Insurance remained voluntary.

In 1941, the Insurance Bureau of the Ministry of Health and Welfare announced the Basic Outline for the Structure of Social Insurance, which set out a comprehensive vision for the future of Japan's social insurance system. The outline proposed a dual structure comprising employment-based insurance and community-based insurance, the realization of universal coverage through compulsory enrolment, and the reduction of benefit disparities through enhanced coverage. To give effect to this vision, legislative reforms were enacted in 1942 to integrate employment-based insurance schemes and strengthen community-based insurance. As a result, decision-making authority over most aspects of healthcare provision—previously dominated by medical associations—was transferred to the government, and National Health Insurance was converted into a compulsory system. Subsequent government-led

campaigns to promote universal enrolment led to the establishment of National Health Insurance associations in 95 per cent of municipalities by the end of fiscal year 1943, achieving what is referred to as the first instance of universal health insurance coverage in Japan.

However, this state-led insurance system was unable to function effectively due to worsening wartime fiscal constraints, shortages of physicians, and shortages of medical supplies. Nevertheless, the institutional foundations established during this period later became an essential basis for the post-war development of Japan's public health insurance system.

Development of the Welfare State: Re-achievement of Universal Health Insurance and Expansion of Healthcare Coverage

Following the end of the Second World War in 1945, under the occupation policies of the General Headquarters (GHQ) of the Allied Powers, National Health Insurance was redefined not as a product of fascism but as a public social security system. In 1948, the National Health Insurance Act was amended to introduce a decentralized structure under which municipalities could establish National Health Insurance schemes through local ordinances on a voluntary basis. As a result, given the severe socio-economic devastation of the post-war period, only a limited number of municipalities were able to implement such ordinances, and by 1956 it was estimated that approximately one-third of Japan's population remained without health insurance coverage.

In response to this situation, momentum grew to enroll all uninsured individuals into National Health Insurance. In 1958, the National Health Insurance Act was revised once again, reclassifying the system as a responsibility of the central government rather than a discretionary municipal function. This revision provided the legal basis for fiscal transfers from the central government to municipalities, enabling supported municipalities to expand and consolidate their National Health Insurance schemes. By 1961, National Health Insurance associations had been established in all municipalities, and Japan is widely regarded as having achieved universal health insurance coverage at that point.^{18,19,20}

Improved affordability significantly increased public demand for healthcare services. However, disparities in benefit levels persisted across different insurance schemes. For example, employed persons covered by employment-based insurance received full coverage of medical costs, whereas National Health Insurance beneficiaries were required to pay 50 per cent of costs out of pocket. In response to societal demands for equity, the healthcare insurance system was progressively expanded throughout the 1970s. Out-of-pocket payments for household heads and family members under National Health Insurance, as well as for dependents under employment-based insurance, were gradually reduced from 50 per cent to 30 per cent. In addition, the High-Cost Medical Expense Benefit System was introduced, under which insurance would reimburse costs exceeding a specified threshold. Furthermore, a system was established whereby public funds covered out-of-pocket medical expenses for older adults. Initially developed by local governments, this approach was later adopted at the

¹⁸ Kitayama, T. (2011). Institutional Development of the Welfare State and Local Government: The Politics of National Health Insurance. Yuhikaku.

¹⁹ Saguchi, T. (1977). History of the Japanese Social Insurance System. Keiso Shobo.

²⁰ Yoshihara, K. and Wada, M. (2008). History of the Japanese Medical Insurance System. Toyo Keizai Inc.

national level. A partial revision of the Elderly Welfare Act in 1972 led to the implementation of the Elderly Medical Care Benefit Scheme in January 1973, the year often referred to as the “first year of welfare.” Under this scheme, individuals aged 70 years and over were able to access medical care, free of charge.

This period was characterized by the expansion of benefits across all insurance schemes, supported by increasing fiscal transfers from the central government. Behind the scenes, however, serious financial deficits emerged, particularly within employment-based insurance schemes covering small and medium-sized enterprises. Proposals to redistribute financial resources from the more stable insurance schemes of large corporations were debated but ultimately not realized. Against the backdrop of rapid economic growth, these fiscal challenges were temporarily resolved through additional government subsidies.

Reorganization of the Welfare State: Institutional Fragmentation and Fiscal Integration

The oil shock of 1973 placed significant constraints on the expansion of welfare states across advanced economies. In Japan, growing concern over rising healthcare expenditure driven by increased use of medical services by older people led to heightened scrutiny of the fiscal sustainability of the public health insurance system. Policy orientation shifted from a gradual reduction of out-of-pocket payments towards zero, to an approach aimed at converging at a certain level of equitable cost-sharing. This policy shift was symbolized by the 1984 revision of the Health Insurance Act, which raised the previously zero co-payment for employed insured individuals to 10 per cent.

At the same time, while new schemes continued to be introduced, the overall system evolved in two contrasting directions: institutionally, multiple schemes became increasingly differentiated and layered, akin to grafting new arrangements onto existing ones; fiscally, however, these schemes became increasingly integrated through inter-scheme financial adjustments.

A pioneering initiative in this process was the enactment of the Health and Medical Services Act for the Aged in 1982. By 1980, expenditure on healthcare for older people had expanded to more than four times its pre-1973 level, raising serious concerns. In particular, the financial strain on National Health Insurance (NHI) became a key issue, as retired individuals transitioned from employment-based insurance to community-based insurance schemes. Although the creation of an age-independent scheme that would separate older people from NHI was considered, it was not realized. Instead, older individuals remained enrolled in their existing insurance schemes, while financial adjustments between insurers were implemented based on factors, such as the number of older beneficiaries. Concurrently, the introduction of modest co-payments for older people marked the end of the era of “free medical care for the elderly”.

In addition, to address structural problems arising from the transfer of retired employees into NHI, thereby placing further strain on its finances, the Retiree Medical Care Scheme was introduced in 1984. This scheme covered medical expenses for individuals and their families who had moved into NHI upon retirement, drawing primarily on contributions from the insurance premiums paid by working

employees and employers. Its objectives were twofold: to mitigate the sudden increase in co-payment rates faced upon retirement, and to alleviate the financial burden borne by other NHI members.

The Health and Medical Services Act for the Aged and the Retiree Medical Care Scheme were subsequently reorganized through the elderly healthcare system reform implemented in 2006. At long last, an age-independent insurance scheme covering all individuals aged 75 and over was established. Upon reaching the eligible age, individuals were required to withdraw from their previous employment-based or community-based insurance schemes and enroll mandatorily in this new system. The financing structure of this scheme consists of approximately 50 per cent public funds (tax revenue), around 10 per cent contributions paid directly by older beneficiaries, and the remaining 40 per cent covered by financial transfers derived from insurance premiums paid by the working-age population. For individuals aged 65 to 74 (the “young-old”), a system similar to the former Health and Medical Services Act for the Aged was established. Under this arrangement, individuals remain enrolled in either employment-based or community-based insurance schemes, while financial adjustment mechanisms operate between insurers.

As community-based insurance schemes saw their fiscal burden from retired older people reduced through these arrangements, employment-based insurance schemes, effectively the primary contributors to the redistribution mechanism, began to voice increasing concern. In response, National Health Insurance adopted a policy aimed at reducing regional disparities in medical expenditure. Furthermore, by incorporating prefectural governments into the financial management of NHI, greater fiscal stability of community-based insurance was pursued. Given that healthcare delivery systems, identified as a major cause of regional disparities, fell under prefectural jurisdiction, a cooperative framework was established in which municipalities and prefectures jointly engaged in the efficient management of community-based insurance.

Improvement of the healthcare delivery system emerged as a new policy challenge, framed in terms of the problem of “social hospitalization”. This concept referred to the excessive use of hospitals for treatment purposes due to shortcomings in long-term care service procedures and user cost-sharing at the time, resulting in inefficient consumption of medical resources. To address this issue, the Long-Term Care Insurance Act was enacted in 1997. As a result, those elements of healthcare for older people that were more care-oriented were transferred from the medical insurance system to the long-term care insurance system. In effect, a portion of the financial burden previously borne by National Health Insurance was carved out and addressed through a separate institutional framework.

Unlike medical care, the utility of long-term care services increases with service volume; accordingly, benefit ceilings based on levels of care need were introduced within the long-term care insurance system. Municipalities were designated as insurers, and premiums were to be financed by individuals aged 65 and over (Category I insured persons) and by individuals aged 40 to 64 who were enrolled in medical insurance schemes (Category II insured persons).

Towards a New Welfare State: Medium- to Long-Term System Governance

In response to changes in demographic structure and socio-economic conditions, various systems have been developed in a fragmented manner; nonetheless, they have remained fiscally interconnected through the shared nexus of healthcare expenditure for older people. Although this approach has been carried forward to the present day, it is widely recognized as fundamentally provisional, and there is growing acknowledgement that the overall architecture of the health insurance system should ideally be addressed in an integrated and comprehensive manner.

Originally, the 1984 revision of the Health Insurance Act stipulated that the integration and unification of the health insurance system should be pursued to ensure “fairness in burden-sharing and equality in benefits”. However, conflicts of interest proved difficult to reconcile, and reforms proceeded only incrementally. From around 2005, concerns over the financial condition of the health insurance system intensified rapidly at the political level, fueling momentum for comprehensive healthcare system reform.

As a result, legislative amendments enacted in 2006 provided not only for the establishment of the previously mentioned elderly healthcare system, but also for the reorganization of long-term care hospital beds, the promotion of cost containment through prevention-oriented policies, and the restructuring and consolidation of insurers at the prefectural level. Although full integration of the health insurance system was not achieved, individual reform programs were systematically organized around overarching reform objectives that transcended individual schemes.

As the institutional framework grew increasingly comprehensive, questions emerged regarding how such a system could be sustained over time. Against the backdrop of sluggish economic growth, raising public contributions proved politically difficult, placing renewed focus on ensuring the fiscal sustainability of the healthcare system. Particularly, reflecting on criticism that healthcare cost reductions during the Koizumi administration had led to a so-called “collapse of healthcare”, the Liberal Democratic Party began engaging opposition parties in discussions on securing stable funding sources.²¹ With the anticipated surge in social security expenditure associated with the “2025 problem” in mind (see Section 1-1), the National Council on Social Security was established in 2008, adopting a political approach that presented benefits and burdens as an integrated package to the public.

Subsequently, Japan experienced a major political transition from Liberal Democratic Party rule to a Democratic Party government. Although the Democratic Party initially sought to significantly expand social security provision, such ambitions were ultimately constrained by insufficient fiscal resources. Through these debates, the necessity of addressing social security benefits and burdens in an integrated manner gained broad acceptance, leading to continued cross-party discussions on comprehensive reform of social security and taxation. As a result, the Social Security System Reform Promotion Act was enacted in 2012 on the basis of bipartisan consensus, and the National Council for

²¹ Tokyo Foundation. Consumption Tax Archive, No. 5: The Fukuda Administration (Latter Part).
<https://www.tkfd.or.jp/research/detail.php?id=3665>

Social Security System Reform was established.²²

Building on the recommendations of this council, the Act on the Promotion of Reforms to Establish a Sustainable Social Security System (the “Program Act”) was enacted in 2013. This legislation specified reform agendas, timelines, and legislative pathways across key policy areas, including measures to address declining birth rates, healthcare and long-term care, and pensions.²³ Since then, healthcare policy has progressed through the sequential consideration of legislation based on the framework outlined in the Program Act. A notable example is the enactment of the 2015 amendment to the National Health Insurance Act, which constituted a major reform with long-term implications for the structure of the health insurance system. By adding prefectural governments as insurers alongside municipalities, this reform significantly expanded prefectural authority and responsibility over both NHI financial management and healthcare delivery systems.

Since the establishment of the National Council on Social Security in 2008, the medium- to long-term governance framework has been maintained. This has included the creation of the Social Security System Reform Promotion Council in 2014, the Council on All-Generation Social Security in 2019, and the Council for the Construction of an All-Generation Social Security System in 2021. These bodies have articulated an overall vision for social security policy, employing a model whereby target years are set on the basis of social, economic, and demographic indicators, comprehensive discussions are held on the future configuration of the social security system, and healthcare policies are subsequently implemented in accordance with those conclusions.

1.4 Background | Key Policies

Year	Policy	Description
1922	Enactment of the Health Insurance Act	The establishment of the first state-led insurance scheme targeting salaried employees and other categories of employed workers with a fixed level of income.
1938	Enactment of the National Health Insurance Act Establishment of the Ministry of Health and Welfare	Establishment of a voluntary, municipality-administered National Health Insurance (NHI) scheme targeting farmers, the self-employed, retirees, and other non-employed persons who were not covered by the Health Insurance Act.

²² Seike, A. (2023). “Towards a Social Security System that Increases the Number of Supporters.” Policy Research Institute, Ministry of Finance. https://www.mof.go.jp/public_relations/finance/202304/202304o.pdf

²³ Nakamura, S. (2021). “What Was the Integrated Reform of Social Security and Tax? — The Aspect of Enhancing and Stabilising Social Security.” Social Security Research, 2021, Vol. 5, No. 4, pp. 435–448. <https://www.ipss.go.jp/syoushika/bunken/data/pdf/sh21030102.pdf>

1939	Enactment of the Employees' Health Insurance Act	Establishment of an insurance scheme for salaried workers employed by companies in sectors such as finance.
1942	Amendment of the Health Insurance Act	Integration of the Employees' Health Insurance Act into the Health Insurance Act and introduction of a co-payment system.
1948	Enactment of the Medical Care Act	Establishment of regulations governing the opening, management, operation, scale, and staffing of hospitals, clinics, and other medical institutions.
1958	Amendment of the National Health Insurance Act	Municipalities were mandated to operate National Health Insurance, and enrolment became compulsory for those not covered by employees' health insurance or other schemes.
1961	Achievement of Universal Health Insurance Coverage	- Realized through the 1958 amendment to the National Health Insurance Act, which made municipal operation of NHI compulsory. - Patient co-payments were set as follows: no co-payment for insured employees, 50% for dependants, and 30% for National Health Insurance members. - Introduction of the High-Cost Medical Expense Benefit System.
1963	Enactment of the Elderly Welfare Act	- Establishment of special nursing homes for older persons. - Legal institutionalization of home helpers (elderly home-care workers).
1972	Amendment of the Elderly Welfare Act	- Introduction of free medical care for older persons. - Establishment of a new system for individuals aged 70 and over, under which medical care became free for almost all persons in this age group. - Reduction of co-payment levels not only for older persons but also for other National Health Insurance members.
1973	Amendment of the Health Insurance Act	- Establishment of the Elderly Medical Expense Benefit System. - Standardization of fixed-rate national government subsidies for Government-Managed Health Insurance schemes.
1982	Enactment of the Health and Medical Services Act for the Elderly	Termination of free medical care for persons aged 70 and over and introduction of a system requiring modest co-payments.

		Provision that medical expenses for older persons be financed through financial adjustment among insurers.
1985	First Revision of the Medical Care Act	Introduction of prefecture-level medical care plans to manage hospital bed capacity.
1990	Revision of Eight Welfare-Related Acts	Mandated formulation of municipal plans for elderly health and welfare services.
1993	Second Revision of the Medical Care Act	Establishment of the system of Advanced Treatment Hospitals and long-term care bed categories.
1997	Enactment of the Long-Term Care Insurance Act Third Revision of the Medical Care Act	- Launch of a system guaranteeing medical and long-term care costs for elderly persons requiring care. - Partial alleviation of the burden on caregivers and response to the needs of an ageing society. - Establishment of the Community Healthcare Support Hospital system. - Legal institutionalization of informed consent.
2000	Act Partially Amending the Health Insurance Act and Related Acts	- Revision of the High-Cost Medical Expense Benefit System. - Revision of the upper limit of health insurance premium rates. - Abolition of partial co-payments for pharmaceuticals for older persons. - Revision of co-payment requirements for older persons.
	Fourth Revision of the Medical Care Act	- Mandatory notification of hospital bed classifications (general beds and long-term care beds) to improve inpatient medical care. - Introduction of mandatory two-year postgraduate clinical training following medical licensure. - Legal obligation for all medical institutions to establish medical safety management systems.
2002	Act Partially Amending the Health Insurance Act and Related Legislation	- Revision of patient co-payment levels - Introduction of a total remuneration-based system for health insurance premium calculations - Increase in the premium rate for government-managed health insurance - Revision of the method for calculating contributions to elderly medical care expenditure - Measures to strengthen the financial foundation of the National Health Insurance system

2005	Amendment to the Long-Term Care Insurance Act	• Establishment of new preventive benefits and community support services to create a prevention-oriented system • Revision of facility benefits, whereby food and accommodation costs at long-term care facilities were excluded from insurance coverage, with supplementary benefits introduced for low-income users • Creation of a new service framework, including the establishment of community-based services, expansion of residential services, development of a community-based integrated care system, strengthened support for persons with moderate to severe care needs, and clearer role-sharing and coordination between medical and long-term care services • Review of burden-sharing and system operation, including more finely calibrated premium levels for Category I insured persons reflecting ability to pay, revision of care-needs certification, strengthening of insurer functions, and review of cost-sharing ratios
2006	Medical System Reform	• Establishment of a new medical care system for late-stage elderly persons aged 75 and over • Establishment of a public corporation to transfer the management of government-managed health insurance for employees of small and medium-sized enterprises from the national government to prefectural governments
	Act Partially Amending the Health Insurance Act and Related Legislation	• Formulation of medical cost optimization plans aimed at medium- to long-term cost containment, including measures addressing lifestyle-related diseases and prolonged hospitalization • Review of the content and scope of insurance benefits • Abolition of long-term care medical facilities • Establishment of a new medical care system for the elderly
	Fifth Revision of the Medical Care Act	• Promotion, at the prefectural level, of the provision of medical-related information to patients and other service users
2008	Act Partially Amending the Long-Term Care Insurance Act and the Elderly Welfare Act	• Development of management systems to ensure legal compliance by long-term care service providers • Introduction of a prior notification system for suspension

		or closure of long-term care service providers • Obligation to secure continuity of services in cases of service suspension or closure
	Cabinet Order Partially Amending the Enforcement Order of the Health Insurance Act and Related Orders	• Revision of the standard amounts used for calculating high-cost medical care benefits • Establishment of eligibility requirements and benefit amounts for combined high-cost medical and long-term care benefits, as well as combined calculation standards
	Compilation of the Report of the National Council on Social Security	• Introduction of the hospital bed function reporting system and formulation of regional healthcare visions • Strengthening of the role of prefectural governments and transfer of insurer responsibility for National Health Insurance to the prefectural level • Review of the systems governing medical corporations and social welfare corporations • Construction of networks integrating medical and long-term care services, centered on the community-based integrated care system • Financial support to promote reforms of medical and long-term care service delivery systems • Consideration of measures to train general practitioners and raise public awareness, review professional roles within healthcare occupations, establish team-based care, and create systems for continuous data collection and ongoing reassessment • Stabilization of financial foundations and ensuring fairness in the public burden associated with insurance premiums • Prioritization and efficiency improvements in medical benefits, including appropriate definition of the scope of care
2009	Cabinet Order Partially Amending the Enforcement Order of the Health Insurance Act and Related Orders	• Revision of the lump-sum childbirth and childcare allowance and family childbirth and childcare allowance (increase of ¥40,000)
2011	Act to Partially Amend the Long-Term Care Insurance Act, etc., to Strengthen the Foundations of Long-Term Care Services	• Promotion of comprehensive support for persons requiring long-term care, etc., through strengthened coordination between medical care and long-term care, integrating healthcare, long-term care, prevention,

		housing, and daily living support services (the Community-based Integrated Care approach). • Formulation of Long-Term Care Insurance Service Plans for each daily living area based on the identification of local needs and challenges; establishment of 24-hour regular and on-demand response services, as well as composite services. • Extension of the deadline for the abolition of long-term care medical beds. • Promotion of the supply of service-inclusive housing for older persons.
2012	Amendment to the National Health Insurance Act	• Transfer of fiscal management responsibility for National Health Insurance to prefectures, with the aims of stabilizing the financial base and correcting disparities in insurance premiums.
2013	Act to Partially Amend the Health Insurance Act, etc.	• Implementation of measures to extend by two years the fiscal support provided to the Japan Health Insurance Association (Kyōkai Kenpō) from 2010 to 2012 (i.e. (i) the national treasury subsidy ratio and (ii) the method for sharing contributions to support the medical care system for the latter-stage elderly). • Extension for two years of the measure to raise the national treasury subsidy for Kyōkai Kenpō from 13% to 16.4%.
2013	Establishment of the Social Security Reform Program	• Clarification of items for consideration regarding reforms of the medical care system, the long-term care insurance system, and related schemes. • Establishment of the hospital bed function reporting system and reform of the role and operation of National Health Insurance insurers. • Full application of the total remuneration-based contribution method for support payments for the latter-stage elderly. • Review of co-payment rates for persons aged 70–74. • Review of the High-Cost Medical Expense Benefit System.
2014	Act on the Development of Related Laws to Promote the Comprehensive Securing of	• Establishment of new funds in prefectures, utilizing increased consumption tax revenue, to create new funding mechanisms and strengthen coordination

	Medical and Long-Term Care Services in the Community	between medical care and long-term care. • To ensure efficient and effective regional medical service delivery, medical institutions are required to report the medical functions of their hospital beds (advanced acute, acute, recovery, chronic, etc.) to prefectural governors; based on these reports, prefectures formulate Regional Healthcare Visions—the desired future configuration of regional medical service delivery—within their medical care plans. • To build the Community-based Integrated Care System and ensure fairness in cost-sharing, preventive benefits (home-visit care and day-care services) are transferred to community support projects alongside the enhancement of such projects.
	Cabinet Order to Partially Amend the Enforcement Order of the Health Insurance Act, etc.	• Revision of the amounts of the lump-sum childbirth and child-rearing allowance and related benefits. • Revision of the calculation standard amounts for the High-Cost Medical Expense Benefit and the High-Cost Medical and Long-Term Care Combined Benefit.
	Sixth Revision of the Medical Care Act	• Promotion of functional differentiation and coordination of hospital beds through the introduction of the bed function reporting system and the formulation of Regional Healthcare Plans • Measures to secure healthcare professionals, including physicians and nurses • Introduction of a renewal system for the designation of Advanced Treatment Hospitals • Measures to improve the working conditions of healthcare professionals • Promotion of home-based medical care • Further promotion of clinical research • Establishment of mechanisms for the investigation of medical accidents • Review of the medical corporation system
	Enactment of the Act on the Comprehensive Securing of Medical and Long-Term Care Services	• Securing efficient and effective healthcare delivery systems at the regional level • Construction of a community-based integrated care system and ensuring fairness in cost-sharing

2015	Enactment of the Act Partially Amending the National Health Insurance Act and Related Acts to Establish a Sustainable Medical Insurance System	• Transfer of responsibility for the financial management of National Health Insurance from municipalities to prefectures • Increases in insurance premiums for employees of large corporations and public servants • Decision to introduce “Patient-Requested Medical Care”, allowing the combined use of insured medical treatment and uninsured services
	Seventh Revision of the Medical Care Act	• Establishment of the Regional Medical Cooperation Promotion Corporation system • Review of the medical corporation system
2017	Eighth Revision of the Medical Care Act	• Introduction of provisions concerning governance reform of Advanced Treatment Hospitals • Establishment of regulations on false or exaggerated claims on healthcare institutions’ websites and other media
	Cabinet Order Partially Amending the Enforcement Order of the Health Insurance Act and Related Orders	• Review of the calculation standards for high-cost medical expense ceilings applicable to insured persons aged 70 and over
	Act Partially Amending the Long-Term Care Insurance Act and Related Acts to Strengthen the Community-Based Integrated Care System	• Institutionalization of mechanisms requiring all municipalities to exercise insurer functions and engage in initiatives aimed at supporting independence and preventing deterioration • Creation of new long-term care insurance facilities combining functions such as “routine medical management” and “end-of-life/terminal care” with residential living functions • Increase of the co-payment rate to 30% for particularly high-income individuals among those subject to a 20% co-payment
2018	Prefectural-Level Integration of the National Health Insurance System	• Responsibility for the financial management of National Health Insurance was transferred from municipalities to prefectures, making prefectures the primary entities responsible for financial management

Japanese Health Policy

2. Processes and Key Actors

September 2026

2.1 Processes and Key Actors | Overview of Japan's Governance

Structure

Japan's system of governance operates under the *Constitution of Japan*, which came into force in 1947, and adopts a parliamentary cabinet system. Unlike a presidential system, in which legislative and executive powers are strictly separated, the parliamentary cabinet system is institutionally designed to generate stable political initiative through the fusion of executive authority with the legislature. However, it has often been noted that Japan's actual political practice has taken on characteristics that differ from the leadership model originally envisaged under this system. Rather than the Prime Minister exercising strong top-down leadership to implement bold policy changes, Japanese politics has traditionally been characterized by a governance style in which information is continuously gathered from extensive administrative networks that penetrate all levels of society, and policy coordination is incrementally advanced through bottom-up processes.

Following political reforms from the 1990s onwards, institutional arrangements were put in place to realize a more orthodox form of parliamentary cabinet government, in which legislation and administration are integrated in the conduct of governance. As a result, some Prime Ministers have emerged who were able to demonstrate strong leadership by skillfully utilizing the political institutions and environments created by these reforms. The judiciary, meanwhile, generally refrains from intervening in legislative and executive affairs and is typically accorded a relatively high degree of discretion. Conversely, court rulings, though issued infrequently, tend to be respected by both the legislature and the executive. The following sections examine Japan's governance structure in greater detail.

The Japanese Policy-Making Process²⁴

A defining feature of the parliamentary cabinet system is that the cabinet, which exercises executive authority, is formed on the basis of the confidence of the legislature. In Japan, the Prime Minister is elected by members of the National Diet, who themselves are chosen by the electorate. The Prime Minister then appoints ministers to exercise executive power, creating an interlinked relationship between the Diet and the Cabinet. Consequently, government policies are generally expected to pass through the Diet, and compared with a presidential system, in which legislators and the president are elected separately, authority is institutionally more concentrated in the Prime Minister.

In practice, however, the Cabinet has not frequently exercised its authority in a top-down manner to implement policy. One reason is that the bureaucracy, which ministers were expected to command to actualize policy objectives, in fact possessed such advanced policy-formulation capacity that it was often able to exert influence over ministers themselves. Another reason lies in the long-standing

²⁴ Iio, Jun (2007). *Japan's Governance Structure: From Bureaucratic Cabinet Government to Parliamentary Cabinet Government*. Chūō Kōron Shinsho.

dominance of the Liberal Democratic Party (LDP), that for many years held a majority in the Diet while encompassing diverse political interests. The LDP developed robust internal policy-making and decision-making mechanisms, through which policies were scrutinized and consensus was formed within the party prior to Diet deliberation. By establishing party-wide agreement in advance and ensuring unified support during parliamentary debate, the LDP effectively monopolized the substantive policy-deliberation process. As a result, the ruling party, while ostensibly integrated with the government, came to function as an entity distinct from the Cabinet, retaining a *de facto* veto over government policy.

Under these conditions, policy formulation typically proceeded as follows. When a new policy was required, the relevant divisions within the responsible ministry would first undertake information gathering and solicit opinions. A draft proposal would then be prepared through extensive coordination involving advisory councils composed of industry representatives and academic experts, consultations with other ministries, and discussions with relevant politicians. Once a draft was completed, ministerial officials would visit the ruling party to provide explanations and engage in discussions with ruling-party legislators. These legislators, for their part, would participate actively, drawing on accumulated expertise in their respective policy areas. After passing internal party deliberation and being approved as the final consensus of the ruling party, the bill would be submitted to the Cabinet for formal approval at a cabinet meeting, before being introduced to the Diet. In Japan, once prior screening by the ruling party has been completed, party discipline (so-called *party binding*) typically determines voting behavior, meaning that substantive amendments to government-sponsored bills are rarely made during Diet deliberations.

In this way, post-war Japanese policymaking was characterized by a process in which the bureaucracy and ruling-party legislators absorbed information from the grassroots through surveys, hearings, and petitions, and then coordinated centrally to formulate policies. While this approach was ill-suited to bold policy shifts or cross-sectoral strategic decisions, it was regarded as highly effective in delivering finely calibrated responses within specific policy domains. Particularly during periods of economic growth, when government resources were relatively abundant, close cooperation between the public and private sectors enabled policies aimed at protecting, nurturing, and regulating industries.

Westminster-Style Reforms²⁵

From the 1980s onwards, as economic growth slowed and political corruption scandals came to light, the need for political reform gained widespread recognition. From the 1990s through the early 2000s, a series of reforms were implemented, including electoral reform introducing single-member districts for House of Representatives elections, the strengthening of cabinet functions, and the reorganization of central government ministries. These reforms sought to approximate a more orthodox parliamentary cabinet system, in which voters choose political parties and governments in general elections, and the Prime Minister exercises leadership in governing the Cabinet.

²⁵ Iio, Jun (2007). *Japan's Governance Structure: From Bureaucratic Cabinet Government to Parliamentary Cabinet Government*. Chūō Kōron Shinsho.

These political reforms also altered the policymaking process. On major policy issues, deliberation began to take place within the Council on Economic and Fiscal Policy, an advisory body to the Prime Minister established in 2001, enabling agenda-setting that was not dependent on prior bureaucratic coordination. Institutional mechanisms were also created to allow reform initiatives to be proposed and coordinated directly under the Prime Minister's leadership. In some cases, responsibility for key government policies was transferred from individual ministries to central coordinating bodies such as the Cabinet Secretariat.

Nevertheless, the extent to which concentrated authority within the Cabinet can be effectively exercised depends heavily on political circumstances and the governing philosophy of the Prime Minister. While reforms have undoubtedly strengthened cabinet functions and, under certain conditions, enabled top-down policy formulation by the Prime Minister and Cabinet, the traditional Japanese policy-making process has by no means disappeared and continues to coexist with these newer arrangements.

The Role of the Judiciary

In Japan, the judiciary does not routinely exert influence over healthcare policy. Ordinarily, it shows deference to the judgments of the legislative and executive branches and tends to grant them a relatively wide margin of discretion. Conversely, when court rulings are issued, albeit infrequently, they are widely regarded as carrying strong binding force over legislative and administrative actions.

The following section provides an overview of major cases in which judicial decisions have influenced healthcare policy.²⁶

	Case Overview	Judicial Rulings and Legislative / Administrative Responses
Thalidomide Litigation (c. 1960 onwards)	Children were born with severe disabilities, known as <i>thalidomide embryopathy</i> , to mothers who had taken thalidomide (a sedative–hypnotic drug, among other uses) during early pregnancy	• Settlement reached through the courts (62 plaintiffs) • Issuance of the <i>Basic Policy on the Approval of Pharmaceutical Manufacturing, etc.</i> • Introduction of the Adverse Drug Reaction Reporting System²⁷
SMON (Subacute Myelo-Optico-Neuropathy)	Patients developed SMON after taking clioquinol-containing drugs used as intestinal medicines	• Court settlements reached (4,819 plaintiffs) • Revision of the Pharmaceutical Affairs Act (1979)

²⁶ Unless otherwise indicated by specific footnotes, the table below is based on the Ministry of Health, Labour and Welfare (MHLW). *Cases of Litigation Related to Adverse Drug Reactions (Cases Concluded by Settlement)*, available at: https://www.mhlw.go.jp/shingi/2008/06/dl/s0605-4a_0004.pdf

²⁷ A system for reporting adverse drug reactions from companies to the Ministry of Health, Labour and Welfare was introduced through administrative guidance.

Litigation (c. 1970 onwards)		– Introduction of the re-examination system for new pharmaceuticals, among other measures • Enactment of the Pharmaceutical Side-Effect Injury Relief Fund Act (1979) – Establishment of the Pharmaceutical Adverse Drug Reaction Relief System
HIV Litigation (c. 1980 onwards)	Patients with hemophilia and others were infected with HIV after receiving non-heat-treated blood coagulation factor products manufactured from blood collected in the United States and contaminated with HIV.	• Court settlements reached (120 HIV cases; 44 CJD cases) • Revision of the Pharmaceutical Affairs Act – Mandatory compliance with Good Clinical Practice (GCP) for clinical trials²⁸ – Mandatory reporting of overseas public health risk prevention measures • Revisions to the Pharmaceutical Affairs Act and the Blood Act (2002) – Creation of the Specified Biological Products category and strengthened safety measures²⁹ • Enactment of the PMDA Act – Introduction of the Relief System for Infections and Other Injuries Caused by Biological Products
Creutzfeldt–Jakob Disease (CJD) Litigation (c. 1996–2005)	Patients developed CJD after receiving transplants of human dura mater contaminated with CJD pathogens during neurosurgical procedures. The dura mater had been imported from Germany.	• Enactment of the PMDA Act – Introduction of the Relief System for Infections and Other Injuries Caused by Biological Products
Refusal to Designate Medical Institutions for Health Insurance Coverage (2005)	A hospital was established despite a recommendation to suspend its opening due to an excess number of hospital beds under the Medical Care Act and regional medical care plans.³⁰	• The court dismissed the plaintiff's claim seeking revocation of the refusal to designate the hospital as an insured medical institution.
Prohibition of Mixed Medical Treatment	Medical practice was governed by an interpretation that combining insured medical treatment with uninsured medical treatment	• The court dismissed claims asserting that denying insurance coverage for mixed treatment was unlawful.

²⁸ For details of the approval and licensing standards currently required for the use of pharmaceuticals, see Section 5.

²⁹ "Specified biological products" refer to products manufactured using materials derived from humans or other living organisms (excluding plants) for which post-marketing safety measures are required to prevent the occurrence or expansion of public health hazards. Blood products constitute a representative example.

³⁰ Kasagi, Eri et al. (2018). *Social Security Law*. Yūhikaku.

(2011) ³¹	("mixed treatment") was not eligible for insurance coverage.	- An accompanying opinion noted ambiguity and lack of clarity in the national system framework.
Hepatitis C Drug-Induced Injury Litigation (2002 onwards)	Patients were infected with the hepatitis C virus after receiving specified fibrinogen products or specified blood coagulation factor IX products during childbirth or surgery involving massive bleeding.	• Enactment of the Special Measures Act for Hepatitis C³² - Establishment of an early, uniform compensation scheme based on disease severity, regardless of timing of administration³³ • Basic Act on Hepatitis Countermeasures - Establishment of fundamental principles and a comprehensive national framework for hepatitis prevention and control.³⁴
Hansen's Disease Litigation / Hansen's Disease Family Litigation (from 1998 onwards)	Former Hansen's disease patients were subjected to continued forced isolation in sanatoria under the <i>Leprosy Prevention Act</i> .	• Court rulings against the State, in favor of plaintiffs - Patients: 2001 - Family members: 2019 • Enactment of the Basic Act on the Issue of Hansen's Disease (2008)

³¹ Kasagi, Eri et al. (2018). *Social Security Law*. Yūhikaku.

³² Ministry of Health, Labour and Welfare. *Claims for Benefits under the Special Measures Act for Hepatitis C*, available at: <https://www.mhlw.go.jp/content/10901000/001055203.pdf>

³³ To receive benefits, it is necessary to file a lawsuit against the national government and obtain judicial confirmation of eligibility through legal proceedings. In addition, a claim must be submitted to the Pharmaceuticals and Medical Devices Agency (PMDA), together with supporting documentation such as court judgments or settlement agreements.

³⁴ Ministry of Health, Labour and Welfare. *Basic Act on Hepatitis Measures*, available at: <https://www.mhlw.go.jp/wp/hakusyo/kousei/10-2/kousei-data/PDF/22010219.pdf>

2.2 Processes and Actors | The Health Policy Decision-Making Process

Health policy is, unsurprisingly, influenced by changes in Japan's system of governance. This section explains how the process for revising the medical fee schedule has evolved alongside transformations in Japan's governance structure.

Although Japan's healthcare system is largely defined by the public health insurance scheme (see Section 1.2), the core mechanism underpinning this system is the medical fee schedule (*shinryō hōshū*). The medical fee schedule refers to the remuneration received in return for medical services provided. It establishes nationally uniform fees for services delivered by medical institutions and pharmacies. As a result, regulation of the medical fee schedule enables policymakers to steer the behavior of the vast majority of hospitals, clinics, and pharmacies across the country.

Conversely, because the medical fee schedule has a direct and substantial impact on the financial conditions of the healthcare sector as a whole, it has long been a focal point of political contention. Medical fee policy therefore involves a wide range of stakeholders and proceeds through multiple stages before decisions are finalized. In order to accommodate ongoing advances in medical technology while managing the complex and often conflicting interests of stakeholders, a structured and predictable policy-making process is required. In recent years, revisions to the medical fee schedule have, in principle, been conducted once every two years, following a clearly defined timetable.

A broadly similar process exists within the long-term care insurance system; however, this is not discussed here.

The Traditional Process of Medical Fee Revisions^{35,36,37}

In the post-war period, the Central Social Insurance Medical Council (*Chūō Shakai Hoken Iryō Kyōgikai*, hereafter Chuikyo) held extensive authority over medical fee revisions. Chuikyo is an advisory council established within the Ministry of Health, Labour and Welfare and is composed of three groups: representatives of payers (such as insurers), representatives of providers (such as medical associations), and public interest members (including academics).

Notably, despite formally being an advisory body to the Minister of Health, Labour and Welfare, Chuikyo deliberated on and submitted recommendations regarding the rate of revision of the medical fee schedule. This revision rate represents an estimate of the overall increase (or decrease) in national

³⁵ Tanabe, Kuniaki (2021). "The Structure and Process of Decision-Making within the Central Social Insurance Medical Council." *Health Economics Research*, Vol. 33, No. 1.

https://www.ihep.jp/wp-content/uploads/2021/10/Vol.33_No.1_2021_2-0.pdf

³⁶ Ministry of Health, Labour and Welfare. *Summary of the Report of the Expert Panel on the Future of the Central Social Insurance Medical Council*, available at:

<https://www.mhlw.go.jp/shingi/2005/07/dl/s0720-7a1.pdf>

³⁷ Ministry of Health, Labour and Welfare. *Towards a New Start for the Central Social Insurance Medical Council*, available at:

<https://www.mhlw.go.jp/shingi/2005/07/dl/s0720-7b1.pdf>

healthcare expenditure resulting from the revision and has a significant influence on the government's overall budget formulation. In effect, decisions that should ordinarily fall under the remit of the Cabinet or the Ministry of Finance were being determined by a council attached to a single ministry. While Chuikyo as an institution wielded considerable authority, reaching consensus within the council was often extremely difficult. In broad terms, payer representatives, who prioritized the containment of healthcare expenditure, frequently clashed with provider representatives, who tended to favor increased spending. It has been suggested that both sides seek political resolutions by mobilizing members of the Diet or affiliated organizations at times. Among these actors, the Japan Medical Association was widely regarded as possessing particularly strong political influence.

Even after agreement was reached at the macro level on the overall revision rate, detailed decisions still had to be made at the micro level regarding how remuneration would be allocated across individual medical services. At this stage, conflicts sometimes arose even within the provider group itself, as negotiations effectively became competitions for limited resources between clinics and hospitals, or among different medical specialties. The Japan Medical Association was often perceived as being more inclined to protect the interests of clinic owners.

For many years, these deliberations were conducted behind closed doors, resulting in a policymaking process characterized by opacity and closed political bargaining. As governance reforms from the 1990s onwards strengthened the concentration of authority within the Cabinet (see Section 2.1), criticism intensified, particularly following bribery scandals involving Chuikyo, regarding the council's assumption of functions that should properly belong to the executive. These developments culminated in the reform of Chuikyo in 2005, marking a major turning point in the medical fee revision process.

The Reformed Medical Fee Revision Process

Following the 2005 reforms, functions that had previously been concentrated within Chuikyo were redistributed among other institutions, and Chuikyo's role was more clearly defined.³⁸ The revised process operates as follows.

First, within the Cabinet, the overall budgetary framework is established, including the total amount that can be allocated to healthcare expenditure and the overall revision rate for the medical fee schedule. Next, the Social Security Council formulates the "Basic Policy for Medical Fee Revisions" from the perspectives of healthcare delivery and the health insurance system. Subsequently, Chuikyo undertakes detailed revisions of individual fee items and point values in line with this basic policy and compiles the draft medical fee revision.

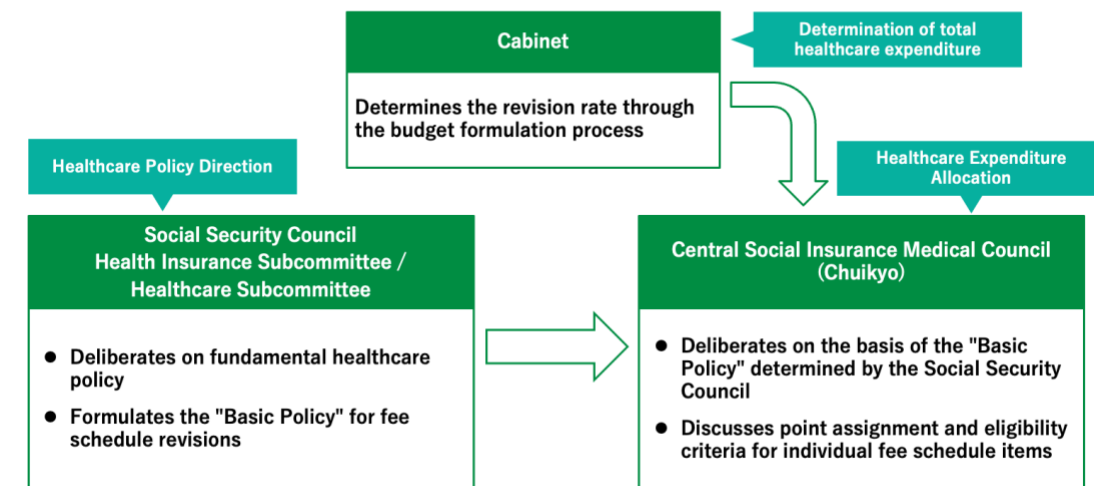
Although these are formally three distinct stages, the Health Insurance Bureau of the Ministry of Health, Labour and Welfare is involved throughout, ensuring consistency and coherence across the

³⁸ Sakai, Masami (2016). "The Structure and Revision of Medical Service Fees." *Journal of the Japanese Society of Internal Medicine*, Vol. 105, No. 12.
https://www.istage.jst.go.jp/article/naika/105/12/105_2320/pdf

entire process and enabling an integrated approach to medical fee revision.³⁹

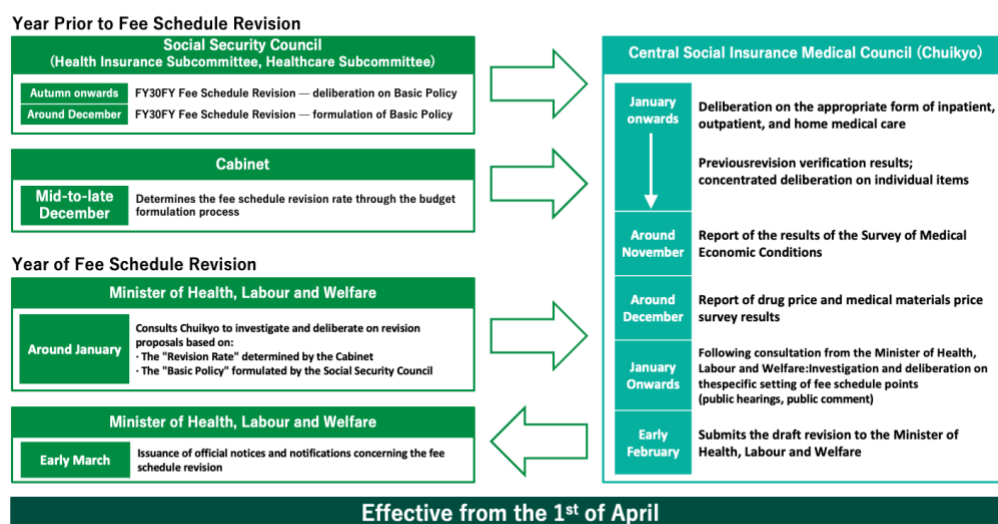
While the logical structure of the process is as described above, the actual two-year deliberation cycle involves some overlap in timing. For example, formulation of the “Basic Policy” by the Social Security Council may precede the Cabinet’s final decision on the revision rate. Within Chuikyo, deliberations typically proceed with an awareness of discussions at the Social Security Council, and it is common for each agenda item to be examined twice over the two-year review period.

Figure 2-2-1 Roles and Relationships of Key Bodies in Fee Schedule Revisions



Note : Prepared with reference to the Ministry of Health, Labour and Welfare, "FY30Fee Schedule Revision Schedule (Draft)".

Figure 2-2-2 Schedule for the Revision of the Medical Fee



Note : Prepared with reference to the Ministry of Health, Labour and Welfare, "FY30Fee Schedule Revision Schedule (Draft)". The schedule is a typical example. The schedule shown is a typical example and does not apply in all cases.

Source: Based on the FY30Fee Schedule Revision Schedule (Draft)" (Ministry of Health, Labour and Welfare)

³⁹ Tanabe, Kuniaki (2021). "The Structure and Process of Decision-Making in the Central Social Insurance Medical Council," *Health Economics Research*, Vol. 33, No. 1. https://www.ihep.jp/wp-content/uploads/2021/10/Vol.33_No.1_2021_2-0.pdf

The Organizational Structure of Chuikyo

As a result of the above reforms, Chuikyo's organizational structure also underwent significant changes. Although attention tends to focus on the General Assembly, which holds final decision-making authority, most substantive deliberation takes place in subcommittees and specialized bodies whose work feeds into decisions made by the General Assembly. These related bodies can be broadly classified into four categories.

The first category consists of four specialized committees. These are established by resolution of the General Assembly to examine technical matters, are composed of General Assembly members, and are chaired by a public interest member. The four committees are the Fee Revision Outcome Verification Committee, the Drug Pricing Committee, the Cost-Effectiveness Evaluation Committee, and the Medical Materials Committee.

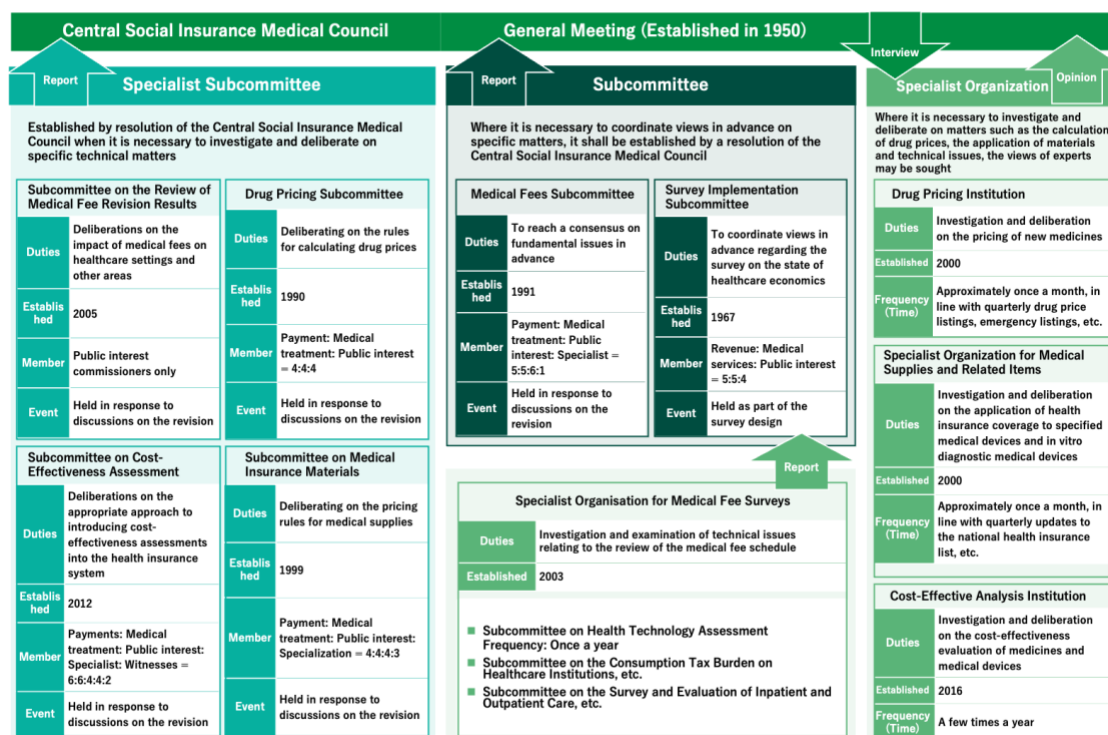
The second category comprises two subcommittees. These are established when prior coordination of views is required on specific issues. They are composed of General Assembly members and chaired by a public interest member. The Medical Fee Fundamental Issues Subcommittee coordinates views between payers and providers based on input from the Technical Expert Organizations for Medical Fee Surveys described below. The Survey Implementation Subcommittee determines survey items for the Medical Economic Survey and coordinates opinions on the survey results.

The third category consists of the Technical Expert Organizations for Medical Fee Surveys. These bodies are established to investigate and examine technical issues related to revisions of the medical fee structure and are composed of healthcare professionals. Divided into several working groups, they deliberate on draft proposals from a technical perspective and report their findings to the Medical Fee Fundamental Issues Subcommittee.

The fourth category comprises three expert organizations that function as advisory bodies when specialist input is required on drug pricing, medical materials, and technical evaluation issues. These bodies include healthcare professionals and other experts and are divided into the Drug Pricing Organization, the Medical Materials Expert Organization, and the Cost-Effectiveness Evaluation Expert Organization. Based on rules approved by the General Assembly, these bodies determine concrete pricing and conduct cost-effectiveness evaluations of individual products.⁴⁰

⁴⁰ Endō, Hisao (2014). "The Process of Determining Medical Service Fees." *Journal of the Japanese Society of Internal Medicine*, Vol. 103, No. 12.
https://www.istage.jst.go.jp/article/naika/103/12/103_2892/pdf/-char/ja

Figure 2-2-3 Internal Structure and Affiliated Organizations of the Central Social Insurance Medical Council



Note: This document has been prepared with reference to the Ministry of Health, Labour and Welfare's 'Schedule for the 2018 Revision of Medical Fees (Draft)'.

2.3 Processes and Players | Actors Involved in Medical Policy Decision-Making

As in other advanced economies, Japan's medical policy is shaped by a wide range of actors, and its decision-making processes involve numerous stakeholders. This section provides an overview of the principal administrative and political bodies engaged in the formulation and determination of medical policy.

Central Government Administrative Bodies

The primary government authority responsible for formulating medical policy is the Ministry of Health, Labour and Welfare (MHLW). However, medical policy in Japan is by no means determined by the MHLW alone.⁴¹ The Ministry of Finance, which has jurisdiction over the national budget, constitutes a particularly influential player. In addition, the Ministry of Economy, Trade and Industry is responsible for healthcare and the pharmaceutical industry, while the Ministry of Education, Culture, Sports, Science and Technology oversees matters relating to basic research. As such, medical policy is shaped

⁴¹ Ministry of Health, Labour and Welfare. *Understanding Insured Medical Treatment (FY2025 Edition)*, available at: <https://www.mhlw.go.jp/content/001521412.pdf>

through interactions among multiple ministries.

Furthermore, against the backdrop of strengthened Cabinet authority, policy developments within the Cabinet Secretariat and the Cabinet Office have also become increasingly significant elements of the medical policy landscape.

Even within the MHLW, medical policy extends well beyond the health insurance system. The supervision of pharmaceutical industry activities, including clinical trials, manufacturing processes, and post-marketing surveillance, also falls within the remit of national administrative bodies. The relevant legal and regulatory frameworks are overseen by a wide range of divisions both within and outside the MHLW. For example, the evaluation of new pharmaceuticals and medical devices is conducted by the Pharmaceuticals and Medical Devices Agency (PMDA),⁴² an Independent Administrative Institution.⁴³

In 2023, administrative functions previously dispersed across bodies such as the Child and Family Affairs Bureau within the MHLW were consolidated with the establishment of the Children and Families Agency, thereby centralizing responsibilities related to child and family policy.

Cabinet Secretariat

The Cabinet Secretariat serves both as a supporting organ of the Cabinet and as an institution that directly assists and advises the Prime Minister. Its responsibilities include managing Cabinet affairs, planning and coordinating key national policies, and collecting and analyzing information. During emergencies, it frequently functions as the central coordinating authority.⁴⁴

In the healthcare domain, the Cabinet Secretariat convenes a range of high-level policy forums, including bodies such as the Medical Digital Transformation (DX) Promotion Headquarters and the Headquarters for the Promotion of Health and Medical Strategies,⁴⁵ reflecting its growing role in cross-sectoral coordination and strategic governance of health policy.

Cabinet Office

Established in 2001 to strengthen the support and advisory structure for the Prime Minister, the Cabinet Office is an organ of the Cabinet headed by the Prime Minister. From a position above individual ministries, it is responsible for the planning, formulation, and overall coordination of key national policies. In addition to housing specialized bodies such as the Headquarters for Healthcare Policy Promotion, it also jointly oversees the Japan Agency for Medical Research and Development (AMED) together with the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the

⁴² An “Independent Administrative Institution” refers to a legal entity established to efficiently and effectively implement administrative functions and projects that are necessary from the perspective of public welfare and socio-economic stability, but which do not require direct implementation by the state itself, or which may not be adequately performed if left entirely to private actors, or which require exclusive implementation by a single entity (Act on General Rules for Incorporated Administrative Agencies, Article 2, Paragraph 1). Comparable systems in other countries include the United Kingdom’s “Executive Agencies”. See: *Comparative Study on Systems of Independent Administrative Institutions in Other Countries*.

https://www.soumu.go.jp/main_content/000537355.pdf

⁴³ Pharmaceuticals and Medical Devices Agency (PMDA). *Overview of PMDA Operations*, available at: <https://www.pmda.go.jp/files/000219906.pdf>

⁴⁴ Cabinet Secretariat. *Overview of the Cabinet Secretariat*. Available at: <https://www.cas.go.jp/jp/gaiyou/index.html>

⁴⁵ Cabinet Office. *Organizational Chart of the Cabinet Office*. Available at: https://www8.cao.go.jp/jinji/saiyo/pamphlet_2021_2.pdf

Ministry of Health, Labour and Welfare (MHLW), and the Ministry of Economy, Trade and Industry (METI).

Japan Agency for Medical Research and Development (AMED)

AMED was established in 2015 as a core institution responsible for medical research and development and for the development of the research environment. By centrally managing medical research and development programs that had previously been conducted separately by MEXT, MHLW, and METI, AMED aims to enable rapid and seamless translation from research to clinical application, as well as to establish systems that ensure the reliable implementation of high-quality clinical research and clinical trials.⁴⁶

Ministry of Health, Labour and Welfare (MHLW)

The Ministry of Health, Labour and Welfare is one of Japan's central government ministries. It was originally established in 1938 as the Ministry of Health and Welfare and was reorganized into its current form following its merger with the Ministry of Labour during the central government reform of 2001.⁴⁷ As of September 2025, the Ministry oversees 21 advisory councils,⁴⁸ eight regional bureaus of health and welfare,⁴⁹ and labour bureaus established in each prefecture. It also has jurisdiction over independent administrative agencies such as the National Hospital Organization, which operates 140 national hospitals,⁵⁰ and the Pharmaceuticals and Medical Devices Agency (PMDA), as well as special public corporations including the Japan Pension Service.

Within the Ministry's headquarters, a wide range of internal departments carry out specialized functions. The principal bureaus involved in the medical policy decision-making process are as follows:⁵¹

- **Health Insurance Bureau:**

This bureau plays a central role in the biennial revision of the medical fee schedule and is responsible for the planning and formulation of policies related to the health insurance system and the late-stage elderly healthcare system. It comprises 13 divisions, each responsible for different insurance schemes and policy areas.

- *Insurance Division / National Health Insurance Division / Elderly Healthcare Division:*

These divisions are responsible for the Health Insurance system (including Seamen's Insurance), the National Health Insurance system, and the Late-Stage Elderly Healthcare Insurance system, respectively.

⁴⁶ Japan Agency for Medical Research and Development (AMED). *Overview of the Agency*. Available at: <https://www.amed.go.jp/aboutus/yakuwari.html>

⁴⁷ Ministry of Health, Labour and Welfare. *The Origins of the Ministry of Health, Labour and Welfare*. Available at: <http://www.mhlw.go.jp/kouseiroudoushou/shigoto/dl/p03.pdf>

⁴⁸ Cabinet Secretariat. *Comprehensive List of Councils*. Available at: https://www.cas.go.jp/jp/gaiyou/jimu/jinjikyoku/satei_01_04_03.html

⁴⁹ Ministry of Health, Labour and Welfare. *List of Locations of Regional Bureaux of Health and Welfare*. Available at: <https://www.mhlw.go.jp/kouseiroudoushou/shozaianai/chihoukouseikyoku.html>

⁵⁰ National Hospital Organization. *About the National Hospital Organization*. Available at: https://nho.hosp.go.jp/about/cnt1-0_000003.html

⁵¹ Ministry of Health, Labour and Welfare. *Main Functions and Responsibilities*. Available at: <https://www.mhlw.go.jp/kouseiroudoushou/shigoto/>

- *Medical Care Division:*

This division plays a major role in matters relating to the medical fee schedule and also serves as the secretariat for the Central Social Insurance Medical Council.

Central Social Insurance Medical Council (Chuikyo)⁵²

The Central Social Insurance Medical Council (hereafter, Chuikyo) is an advisory body to the Minister of Health, Labour and Welfare and is administered by the Health Insurance Bureau of the Ministry. Chuikyo is composed of three groups: representatives of payers, representatives of healthcare providers, and public interest members such as academics, commonly referred to as a “tripartite structure.” It engages in deliberations throughout the year and holds the authority to determine official prices paid from public health insurance, including medical service fees and pharmaceutical prices.⁵³

- **Health Policy Bureau:**

This bureau is responsible for research and policy formulation aimed at establishing high-quality and efficient healthcare delivery systems that respond to changes in population structure and disease patterns, as well as for policies promoting the medical device and pharmaceutical industries. It comprises 20 divisions.

- *Regional Healthcare Planning Division:*

This division oversees matters related to healthcare delivery systems, including regional healthcare planning and issues concerning the uneven distribution of physicians.

- *Pharmaceutical Industry Promotion and Medical Information Planning Division:*

This division is responsible for the overall planning of pharmaceutical industry promotion policies, as well as for matters related to the production, distribution, consumption, improvement, and regulation of pharmaceuticals, quasi-drugs, medical devices, sanitary products, and regenerative medicine products.

- **Elderly Health and Welfare Bureau:**

This bureau is responsible for promoting policies related to elderly care and welfare, including the Long-Term Care Insurance (LTCI) system.

- *Long-Term Care Insurance Planning Division:*

Responsible for the planning and formulation of policies related to the Long-Term Care Insurance system.

⁵² As illustrated by the anecdote that an American executive of a global pharmaceutical company was once advised, “If you were to remember just one Japanese technical term related to healthcare, it should be ‘Chu-i-kyo,’” the Central Social Insurance Medical Council (Chuikyo) is widely regarded as the most important and closely watched government advisory body in healthcare policy. Its deliberations are, in principle, open to the public, and public attendance is permitted. Public attention peaks in the period from the autumn of the preceding year to approximately February, ahead of the biennial medical fee revision implemented each April. During this period, detailed discussions on the revision are conducted, prompting healthcare professionals, journalists, and pharmaceutical company representatives to queue from early morning to secure limited observation tickets. Although seating is often limited to several dozen places, queues of over 100 people forming several hours before the start of proceedings have become a regular feature of Chuikyo meetings.

⁵³ Ministry of Health, Labour and Welfare. *About the Central Social Insurance Medical Council*, <http://www.mhlw.go.jp/shingi/2005/03/dl/s0309-4e3.pdf>

- *Dementia Policy and Community-Based Care Promotion Division:*
Responsible for the planning and development of policies related to dementia.

- **Pharmaceutical Affairs Bureau:**

This bureau is responsible for ensuring the quality, efficacy, and safety of pharmaceuticals, quasi-drugs, medical devices, other sanitary products, and regenerative medicine products. It also oversees blood services and the regulation of narcotics, stimulants, and related substances. In addition, it is responsible for matters relating to the Pharmaceuticals and Medical Devices Agency (PMDA).

- *Pharmaceutical Evaluation and Management Division / Medical Device Evaluation and Management Division / Pharmaceutical Safety Division:*

These divisions provide technical guidance on the production of pharmaceuticals and medical devices, grant manufacturing licenses, approve marketing authorization, and ensure post-market safety.

- *Blood and Blood Products Division:*

Responsible for ensuring the appropriate use of blood products and for promoting blood donation.

Pharmaceuticals and Medical Devices Agency (PMDA)

The Pharmaceuticals and Medical Devices Agency (PMDA) is an independent administrative agency established in 2004.⁵⁴ It is primarily responsible for reviewing the quality, efficacy, and usefulness of new pharmaceuticals and medical devices, as well as for post-marketing safety evaluation and responses to health damage. PMDA operates on the basis of three core functions, namely *relief services for health damage*, *regulatory review and approval*, and *post-marketing safety measures*, which together constitute an integrated risk management framework known as the “Safety Triangle.”⁵⁵ As a result of organizational reforms and strategic initiatives, PMDA has significantly reduced review timelines. The total review period for standard products, which stood at 22 months in 2008, had been shortened to 12.0 months as of the end of September 2023. Similarly, the average review period for priority products was reduced from 15.4 months in 2008 to 6.1 months in 2012, although it had increased to 8.4 months as of September 2023.⁵⁶

Ministry of Finance

The Ministry of Finance is one of Japan’s central government ministries. It maintains regional finance bureaus and customs offices, and oversees the National Tax Agency as an external bureau. Equipped

⁵⁴ Pharmaceuticals and Medical Devices Agency (PMDA). *What is PMDA?*

<https://www.pmda.go.jp/about-pmda/outline/0001.html>

⁵⁵ Pharmaceuticals and Medical Devices Agency (PMDA). *PMDA Operations Guide*.

<https://www.pmda.go.jp/files/000219906.pdf>

⁵⁶ Pharmaceuticals and Medical Devices Agency (PMDA). *FY2023 Business Performance and Future Initiatives*.

<https://www.pmda.go.jp/files/000273928.pdf>

with three principal policy instruments, namely *fiscal policy*, *market-related policy*, and *international policy*, the Ministry plays a critical role across all areas of government by managing the flow of national finances.⁵⁷

- **Budget Bureau:**

As an internal bureau of the Ministry of Finance, the Budget Bureau is responsible for the national budget relating to social security and constitutes one of the most influential actors in medical policy. Expenditure from the general account budget is financed through tax revenues and government bonds and represents a substantial component of total national healthcare expenditure. The Budget Bureau exercises considerable influence, alongside the Health Insurance Bureau of the Ministry of Health, Labour and Welfare, in determining the overall revision rate for biennial medical service fee and pharmaceutical price revisions.⁵⁸

Ministry of Economy, Trade and Industry (METI)

The Ministry of Economy, Trade and Industry is one of Japan's central government ministries. It was originally established in 1949 as the Ministry of International Trade and Industry and was reorganized into its current form following the 2001 central government reform. It maintains regional bureaus of economy, trade, and industry, as well as industrial safety supervision departments, and oversees external agencies including the Agency for Natural Resources and Energy, the Japan Patent Office, and the Small and Medium Enterprise Agency.⁵⁹

In recent years, METI has moved beyond sector-specific industrial policies to pursue integrated domestic and international industrial strategies, playing a leading role in promoting national economic growth strategies.⁶⁰

Healthcare Industries Division

The Healthcare Industries Division seeks to simultaneously extend healthy life expectancy and foster the creation of new industries. Its initiatives focus on disease prevention, early diagnosis and early treatment, as well as preventive care within local communities. Concretely, the Division promotes corporate health management through the implementation of various commendation schemes and undertakes projects aimed at encouraging behavioral change through the utilization of health and medical data. In addition, it places strong emphasis on advancing the medical device industry by identifying five priority fields and providing integrated support across the entire value chain, from product development to international market expansion.⁶¹

⁵⁷ Ministry of Finance. *Recruitment Brochure (Career Track Positions)*.

https://www.mof.go.jp/about_mof/recruit/2025_mofpamphlet.pdf

⁵⁸ Ikegami, N. (2014). *Universal Health Coverage for Inclusive and Sustainable Development: Lessons from Japan*. Japan Center for International Exchange.

<http://www.icie.org/japan/j/pdf/pub/publst/1452/1452all.pdf>

⁵⁹ Ministry of Economy, Trade and Industry. *Organizational Structure of the Ministry of Economy, Trade and Industry*.

https://www.meti.go.jp/intro/pdf/a_soshikizu.pdf

⁶⁰ Ministry of Economy, Trade and Industry. *Mission, Vision and Values of the Ministry of Economy, Trade and Industry*.

<https://www.meti.go.jp/intro/mvv/index.html>

⁶¹ Ministry of Economy, Trade and Industry. *Healthcare Industry Policy at the Ministry of Economy, Trade and Industry*.

https://www.meti.go.jp/policy/mono_info_service/healthcare/01metihealthcarepolicy.pdf

Biochemical Industries Division

The Biochemical Industries Division works to expand the globally emerging bioeconomy market, in line with the *Bioeconomy Strategy* formulated in 2024. Its activities focus on bio-manufacturing and the industrialization of regenerative medicine, cell-based therapies, and gene therapies. Specific initiatives include promoting the development of manufacturing technologies for gene therapies, strengthening vaccine production capacity to prepare for public health emergencies, and supporting drug discovery ventures in securing funding for research and development.⁶²

Ministry of Education, Culture, Sports, Science and Technology (MEXT)

The Ministry of Education, Culture, Sports, Science and Technology is a central government ministry responsible for policies in four key areas: education, science and technology, sports, and culture.⁶³ It oversees external bureaus, such as the Japan Sports Agency and the Agency for Cultural Affairs. Among the independent administrative institutions under its jurisdiction is RIKEN, Japan's sole comprehensive research institute dedicated to the natural sciences. Through the cultivation of human capital and the advancement of knowledge, MEXT plays a central role in contributing to the creation of a prosperous and sustainable future.⁶⁴

Research Promotion Bureau

The Research Promotion Bureau advances basic research and develops research infrastructure in fields such as life sciences and nanotechnology.⁶⁵ In collaboration with the Japan Agency for Medical Research and Development (AMED), the Bureau implements initiatives including the Accelerated Research for Next-Generation Cancer Medicine Program and the Medical Device Research Outcomes Expansion Program. Through these efforts, it promotes technological development via collaboration between academia and industry, while supporting the production of internationally competitive, high-quality research.⁶⁶

Children and Families Agency⁶⁷

The Children and Families Agency is a central government body established in 2023 as an external bureau of the Cabinet Office. It was created to consolidate previously fragmented child-related policies and to function as the government's central coordinating authority in realizing a "child-centered

⁶² Ministry of Economy, Trade and Industry. *Biotechnology Policy*.
https://www.meti.go.jp/policy/mono_info_service/mono/bio/index.html

⁶³ RIKEN (Institute of Physical and Chemical Research). *About RIKEN*.
<https://www.riken.jp/about/>

⁶⁴ Ministry of Education, Culture, Sports, Science and Technology. *Overview of the Ministry of Education, Culture, Sports, Science and Technology*.
https://www.mext.go.jp/b_menu/b003.htm

⁶⁵ Ministry of Education, Culture, Sports, Science and Technology. *Organizational Structure*.
https://www.mext.go.jp/b_menu/soshiki2/top.htm

⁶⁶ Ministry of Education, Culture, Sports, Science and Technology. *Programs Related to Life Sciences Research*.
https://www.mext.go.jp/a_menu/lifescience/bioethics/mext_02555.html

⁶⁷ Children and Families Agency. *Organizational Information*.
<https://www.cfa.go.jp/about>

society.” The Agency is responsible for planning and formulating core policies related to creating environments that support healthy early childhood development and providing assistance for child-rearing within families.

Bureau for Child Development

The Bureau for Child Development oversees policies related to maternal and child health, including support for pregnancy and childbirth, as well as measures to ensure children’s safety. Its mandate is to support the healthy development of all children. Specific initiatives include assistance for infertility treatment and the dissemination of appropriate knowledge and information to expectant and new mothers.⁶⁸

Bureau for Support

The Bureau for Support provides seamless and comprehensive assistance to children and families facing a wide range of challenges, overcoming barriers related to age and institutional frameworks. Its responsibilities include support for children with disabilities and measures to address child poverty.

Local Administrative Bodies

Prefectural Governments

Prefectural governments play a central role in public health insurance, particularly with regard to the optimization of medical expenditure. In recent years, prefectures themselves have assumed responsibility as insurers under the National Health Insurance system, undertaking wide-area insurance management and fiscal coordination. In addition, they are responsible for developing disease- and service-specific healthcare plans,⁶⁹ formulating regional healthcare visions,⁷⁰ and serving as the primary authorities for organizing healthcare delivery systems. Prefectures also conduct supervision and on-site inspections of medical institutions, issue licenses for pharmaceutical sales businesses, and provide oversight and guidance to ensure the appropriate sale and management of pharmaceuticals.

Municipal Governments

Municipal governments serve as insurers for the National Health Insurance and Long-Term Care Insurance schemes, and are responsible for managing enrolment eligibility, collecting insurance

⁶⁸ Children and Families Agency. *Policies on Maternal and Child Health, Infertility, and Recurrent Pregnancy Loss*.
<https://www.cfa.go.jp/policies/boshihoken>

⁶⁹ Ministry of Health, Labour and Welfare. *Medical Care Plans*.
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuu_keikaku/index.html

⁷⁰ The Regional Healthcare Vision is a strategic framework designed to ensure the efficient provision of high-quality and appropriate medical care by promoting functional differentiation and coordination among medical institutions. It is formulated in response to medium- to long-term changes in population structure and in both the qualitative and quantitative dimensions of regional healthcare needs. Prefectural governments are required to formulate medical care plans every five years in order to realize this vision. The implementation of these plans involves a wide range of actors, including municipalities and other local government bodies, as well as diverse stakeholders across the healthcare sector.

premiums, and administering benefits. In addition, they collaborate at the prefectural level to operate the Late-Stage Elderly Medical Care System through wide-area administrative arrangements.

In their capacity as insurers, municipalities implement specific health check-ups and specific health guidance programs, as well as a range of health promotion initiatives, including cancer screening programs. Furthermore, they play a central role in promoting coordination and integration among healthcare, long-term care, and welfare services at the community level.

Public Health Centers

Public health centers constitute a core institutional pillar supporting the health of local residents, undertaking functions such as disease prevention and the promotion of environmental and public hygiene.^{71,72} Pursuant to the Regional Health Act, public health centers are established by local governments of a certain scale, including prefectures, designated cities, core cities, and special wards. Drawing on a high level of professional expertise, public health centers fulfil a wide range of healthcare and public health functions, including the licensing and supervision of medical institutions, food hygiene regulation, pharmaceutical and veterinary public health oversight, provision of specialized public health services, and technical support for municipalities. In municipalities that do not meet the criteria for establishing a public health center, municipal health centers may be established instead.

Other Stakeholders

Political Parties

Political parties play an exceptionally important role in healthcare policymaking.⁷³ Each party adopts a distinct stance on healthcare policy issues, reflecting differing ideological orientations and policy priorities. Figure 2-2-4 presents the results of a questionnaire survey administered to candidates in the 2024 House of Representatives election and the 2025 House of Councilors election.

The survey asked respondents to indicate their level of agreement, on a five-point scale ranging from support to opposition, with the statement: *“Benefits for pensions and medical care should be restrained below current levels.”* The average responses were aggregated and analyzed by political party, thereby illustrating inter-party differences in policy preferences regarding social security expenditure.

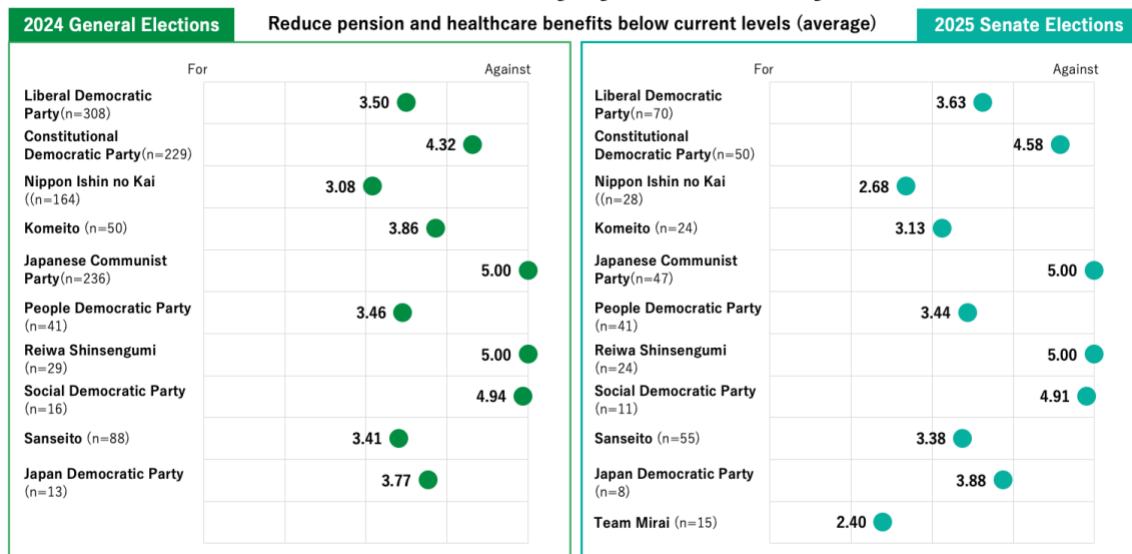
⁷¹ Ministry of Health, Labour and Welfare. *Community Health*.
<http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/tiiki/index.html>

Note that general municipalities (i.e. those other than core cities) are not permitted to establish public health centers; consequently, community health activities in such municipalities are undertaken by municipal health centers.

⁷² The organizational structure of public health centers is centered on a Director of the Public Health Centre (who must hold a medical or dental qualification; see Article 7 of the Community Health Act), supported by specialized professionals in areas such as medical hygiene, environmental hygiene, mental health, and maternal and child health (including public health nurses, pharmacists, and registered dietitians).

⁷³ Data from the University of Tokyo Taniguchi Laboratory–Asahi Survey of Politicians were used, based on surveys conducted during the 2024 House of Representatives election and the 2025 House of Councilors election.

**Figure 2-2-4 Views of Candidates in National Elections
on Social Security by Political Party**



Note: 1 indicates support, 5 indicates opposition. As of the 2024 House of Representatives election, "Team Mirai" did not exist. "No response" and candidates from various factions or standing as independents have been excluded.

Source: University of Tokyo, Oguchi Laboratory and Asahi Shimbun survey data; Survey of politicians regarding the 2024 House of Representatives election and the 2025 House of Councillors election

Liberal Democratic Party (LDP)

Since its founding in 1955, the Liberal Democratic Party (LDP) has served as the ruling party for much of Japan's post-war period.⁷⁴ Owing to its sustained position in government, the LDP is widely regarded as a central stakeholder in healthcare policymaking. In particular, the party has maintained close relationships with professional associations such as the Japan Medical Association and various industry groups, thereby exerting significant influence over health policy formulation and implementation.

Within the LDP, so-called *zoku giin*, legislators with specialized expertise and long-standing involvement in specific policy areas, have traditionally wielded considerable influence over both policy decision-making and execution.⁷⁵ In the healthcare sector, members commonly referred to as *kōrō zoku* (health and labour policy groups) are known to exercise substantial influence over policies under the jurisdiction of the Ministry of Health, Labour and Welfare.

Societal Groups

In addition to governmental bodies and political parties, a wide range of societal stakeholders hold vested interests in healthcare policy and actively participate in the policy formation process. Key societal groups with strong relevance to healthcare policy include industry associations, health insurance-related organizations, and patient groups.

Representative industry associations include the Japan Medical Association, the Japan Dental

⁷⁴ Since its founding, the Liberal Democratic Party (LDP) has remained almost continuously in power as the governing party, with the exception of an eleven-month period between 1993 and 1994 and a period of approximately three years between 2009 and 2011.

⁷⁵ Iio, Jun (2007). *Japan's System of Governance: From a Bureaucratic Cabinet System to a Parliamentary Cabinet System*. Chūō Kōron Shinsha.

Association, the Japan Pharmaceutical Association,⁷⁶ the Japan Nursing Association, and the Japan Pharmaceutical Manufacturers Association. Health insurance–related organizations include bodies such as the National Health Insurance Federation and the Social Insurance Medical Fee Payment Fund. Patient groups are typically organized around specific diseases and focus primarily on activities, such as peer support and the dissemination of disease-related information. Many of these organizations do not regard direct engagement in policymaking as their primary objective.

Japan Medical Association (JMA)

The Japan Medical Association (JMA) is an organization to which approximately 51.6 per cent of physicians in Japan⁷⁷ belong and is widely considered the most influential interest group in the field of healthcare policy. Through its close relationships with government officials, administrative bodies, and the Liberal Democratic Party, the JMA engages in activities aimed at safeguarding physicians' professional autonomy and occupational interests.⁷⁸

In addition, the JMA operates a political organization, the Japan Medical Federation, which for many years has successfully supported organizational candidates in elections to the House of Councilors. Several members of the Central Social Insurance Medical Council (*Chūō Shakai Hoken Iryō Kyōgikai*), the body responsible for determining medical service fees, are selected from among JMA representatives. Beyond formal institutional settings such as the Council, the JMA continues to engage actively in informal advocacy and lobbying activities. These efforts are widely regarded as exerting substantial influence over the drafting of healthcare-related legislation and deliberations on medical fee revisions.

⁷⁶ It should be noted that the Japan Medical Association, the Japan Dental Association, and the Japan Pharmaceutical Association are collectively referred to as the “Three Medical Associations” (*Sanshikai*), and they are regarded as having a relatively strong presence among healthcare-related organizations.

⁷⁷ Japan Medical Association. *Prefectural Membership Rates of Medical Associations for FY2024 (as of January 2025)*.

⁷⁸ Ikegami, Naoki (2014). *Universal Health Coverage for Inclusive and Sustainable Development: Lessons from Japan*. Japan Center for International Exchange.

<http://www.icie.org/japan/j/pdf/pub/publst/1452/1452all.pdf>

Japanese Health Policy

3. Health Insurance System

September 2026

3.1

Health Insurance System | Japan's Health Insurance System

Overview of the Health Insurance System

The Constitution of Japan stipulates the right of citizens to maintain a minimum standard of living and clearly establishes the obligation of the State to develop the necessary environment, including the construction of social security systems. Within the health and medical care sector, the public health insurance system constitutes a core component of social security. Its principal characteristics are universal health insurance coverage and free access.

Universal health insurance refers to the principle that, in principle, all residents are enrolled in some form of public health insurance scheme. Regardless of nationality, all individuals who are recognized as residing in Japan for a period exceeding three months are required to enroll in a public health insurance scheme. The specific public health insurance scheme to which an individual belongs is determined by factors such as occupation, age, and place of residence, and cannot be freely chosen by the individual. Furthermore, where the insured person is not the head of the household, enrolment is determined based on the occupation, age, and place of residence of the household head.

Irrespective of the health insurance scheme to which an individual belongs, patients are free to choose medical institutions and the frequency of consultations at their own discretion. This system is referred to as “free access.” As the vast majority of medical institutions in Japan are registered as providers under the public health insurance system (insured medical institutions), insured individuals are able to receive necessary medical services with a uniform level of cost-sharing, regardless of their insurance scheme (see Section 1.2).

Status of the Various Health Insurance Schemes

Japan has more than 3,000 insurers, broadly classified into three categories: employment-based insurance, community-based insurance, and the Medical Care System for the Latter-Stage Elderly. Individuals aged 75 years and over are enrolled in the Medical Care System for the Latter-Stage Elderly. Those under the age of 75 are enrolled either in employment-based insurance or community-based insurance. Community-based insurance functions as a safety net for individuals who are not eligible for any other public medical insurance scheme.

Employment-Based Insurance

Employment-based insurance primarily provides medical coverage for regular employees and their family members. It should be noted, however, that not all regular employees are eligible. For example, individuals employed by establishments with fewer than five employees are excluded from employment-based insurance and are instead enrolled in community-based insurance. Insurance premiums are calculated by applying the premium rate to the standard monthly remuneration, which

categorizes the monthly wages and other remuneration received from the employer into predetermined income brackets.

Employment-based insurance is mainly divided into two types: Health Insurance Societies and the Japan Health Insurance Association (Kyōkai Kenpō).⁷⁹ As of the end of March 2023, there were 1,383 Health Insurance Societies, all of which are public corporations established under the Health Insurance Act. These include societies established by a single company (single-company societies) and those formed by employers within the same or similar industries (general societies). As of the end of March 2023, the total number of insured persons was 28.2 million.

Kyōkai Kenpō is a single nationwide insurer established under the Health Insurance Act to provide coverage for employees and their families working in small- and medium-sized enterprises for which establishing a Health Insurance Society is difficult. However, premium levels vary by prefectural branch. In addition to premiums paid by insured persons, premiums transferred from Health Insurance Societies and government subsidies constitute the main sources of funding for Kyōkai Kenpō. As of the end of March 2023, the number of insured persons stood at 39.44 million. In cases where a Health Insurance Society is dissolved due to financial difficulties or other reasons, its insured members are transferred to Kyōkai Kenpō. In this respect, Kyōkai Kenpō fulfils a safety-net function within the employment-based insurance system.

Mutual Aid Associations are insurers established under the respective Mutual Aid Association Acts for national public servants and related groups. As of the end of March 2023, there were 85 such associations, with a total of 9.83 million insured persons. As with Health Insurance Societies, premium levels vary depending on the specific Mutual Aid Association.⁸⁰

Community-Based Insurance

The National Health Insurance (NHI) scheme is a health insurance system primarily intended for the self-employed, the unemployed, and retirees under the age of 75. In other words, it functions as a safety net for health insurance coverage by enrolling residents who are not covered by any other medical insurance scheme.

While municipalities were originally the sole insurers of the NHI, prefectural governments were added as insurers from fiscal year 2018. As a result, the system is now administered through a two-tier structure in which prefectures and municipalities share responsibilities. Prefectures play a central role in ensuring stable fiscal management and the efficient operation of the scheme. Municipalities, by contrast, undertake locally tailored activities in close relationship with residents, including eligibility management, the provision of insurance benefits, the determination of premium rates, the assessment and collection of premiums, and the implementation of health promotion programs.

Compared with employment-based insurance, the disease risk among insured persons is higher and income levels are lower, and consequently the financial condition of community-based insurance is a

⁷⁹ Health Insurance Association Federation. *Basic Knowledge of the Medical Insurance System*.

http://www.kenporen.com/health-insurance/m_knowledge/

⁸⁰ Ministry of Health, Labour and Welfare. *Basic Materials on Medical Insurance: Status of Medical Expenditure, FY2022*.

https://www.mhlw.go.jp/content/kiso_r04.pdf

persistent concern. Owing to factors such as the relatively advanced age structure of enrollees, low-income levels, and low premium (tax) collection rates, the scheme may be characterized as financially unstable.⁸¹ Unlike employment-based insurance, in which premiums are shared equally between employers and employees, insured persons under community-based insurance must bear the full cost of premiums themselves, resulting in a relatively high premium burden in relation to income. Premium rates are determined on a regional basis.

The Healthcare System for the Latter-Stage Elderly

As noted in Section 1.3, the Medical Care System for the Latter-Stage Elderly was introduced in 2008 and covers all individuals aged 75 and over. Under this system, there is no distinction between dependents and insured persons; all participants are insured in their own right. The scheme is administered by wide-area associations formed by municipalities at the prefectural level.

Premiums are collected through automatic deductions from individuals' pension benefits. However, premiums account for only around 10 per cent of total revenue, and the system is therefore sustained through public funding and fiscal adjustments with the two aforementioned medical insurance schemes.⁸²

Medical Benefits and Patient Cost-Sharing

Although Japan's public health insurance system is divided into multiple schemes, the content of medical benefits and the cost-sharing rates borne by patients are standardized. This standardization ensures equity of access. In principle, the scope of medical benefits is the same across all public health insurance schemes, and thus disparities in benefit entitlements based on insurance affiliation are largely absent. The public health insurance system broadly covers standard medical treatments, while advanced medical technologies are progressively included once their effectiveness and safety have been verified. As a result, it is generally considered possible to receive appropriate medical care without enrolling in supplementary private insurance.

The standard patient co-payment rate for medical expenses is set at 30 per cent across insurance schemes. However, age-based reductions apply: children under six years of age (prior to compulsory schooling) are subject to a 20 per cent co-payment, individuals aged 70 to 74 also pay 20 per cent, and low-income individuals aged 75 and over pay 10 per cent.⁸³ Depending on income level, some individuals may not qualify for these reduced rates. In addition, certain health insurance societies and local governments operate programs that subsidize part of patients' out-of-pocket costs. A representative example is the municipal child medical expense subsidy program.

⁸¹ Ministry of Health, Labour and Welfare. *On Reform of the Medical Insurance System*. https://www.kantei.go.jp/jp/singi/syakaihosyou_kaikaku/dai4/siryou2.pdf

⁸² Ministry of Health, Labour and Welfare. *Medical Insurance in Japan*. http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html

⁸³ Ministry of Health, Labour and Welfare, Japan's Medical Insurance System. <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000172084.pdf>

The High-Cost Medical Expense Benefit System

To prevent excessive financial burdens on households when medical expenses become high, the High-Cost Medical Expense Benefit System provides reimbursement for amounts exceeding a monthly out-of-pocket ceiling. The ceiling varies according to the insured person's age and income level. For example, for insured persons under the age of 69 with an annual income of approximately ¥3.7 million to ¥7.7 million, the monthly ceiling is calculated as ¥80,100 plus 1 per cent of the amount exceeding ¥267,000 in medical expenses. This system plays a significant role in protecting patients from financial risk (financial risk protection).⁸⁴

In fiscal year 2022, benefit payments under this system amounted to approximately ¥2.13 trillion for those under the age of 75 and approximately ¥836.2 billion for those aged 75 and over. Over the ten-year period from 2012 to 2022, both the number of claims and the total amount paid increased by approximately 1.37 times. Overall, expenditures under the High-Cost Medical Expense Benefit System have continued to rise, and discussions are underway regarding revisions to the out-of-pocket ceilings.⁸⁵

Revenue and Expenditure by Health Insurance Scheme

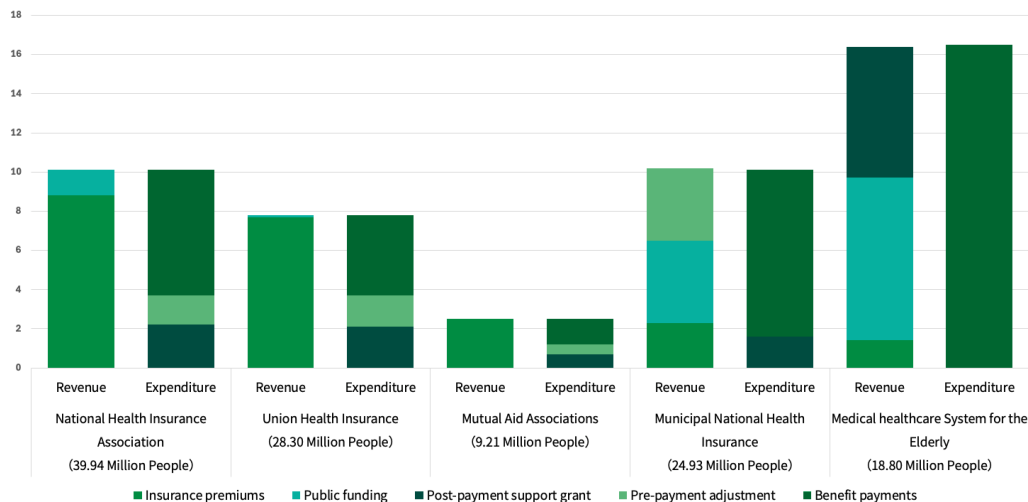
As shown in Figure 3-1-1, expenditures by the Japan Health Insurance Association (Kyōkai Kenpō), society-managed health insurance, and mutual aid associations, such as contributions for the support of the latter-stage elderly, contributions for the pre-latter-stage elderly, and retirement-related contributions, are transformed through inter-insurer fiscal adjustment into revenues for other schemes. These include grants for the latter-stage elderly medical care system, grants for pre-latter-stage elderly coverage within municipal NHI, and retirement-related grants.

Figure 3-1-1 also illustrates that the proportion of revenue derived from insurance premiums and national government contributions, as well as the proportion of expenditure devoted to benefit payments, varies considerably across insurers. As is evident from the table, national government contributions account for a substantially larger share of revenue than premium income in both the latter-stage elderly medical care system and the NHI. This heavy reliance on central government funding underscores the severity of the challenges facing their fiscal management.

⁸⁴ Ministry of Health, Labour and Welfare. *For Those Using the High-Cost Medical Expense Benefit System*. <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000161153.pdf>

⁸⁵ Ministry of Health, Labour and Welfare. *High-Cost Medical Expense Benefit System*. <https://www.mhlw.go.jp/content/12401000/001492935.pdf>

**Figure 3-1-1 Revenue and Expenditure by Health Insurance Scheme
(Financial Year 2022)**



Note: All figures are in trillions of yen

Source: Ministry of Health, Labour and Welfare, 'Overview of Public Expenditure by Scheme (FY2022)' https://www.mhlw.go.jp/content/12400000/mieruka_2022.pdf

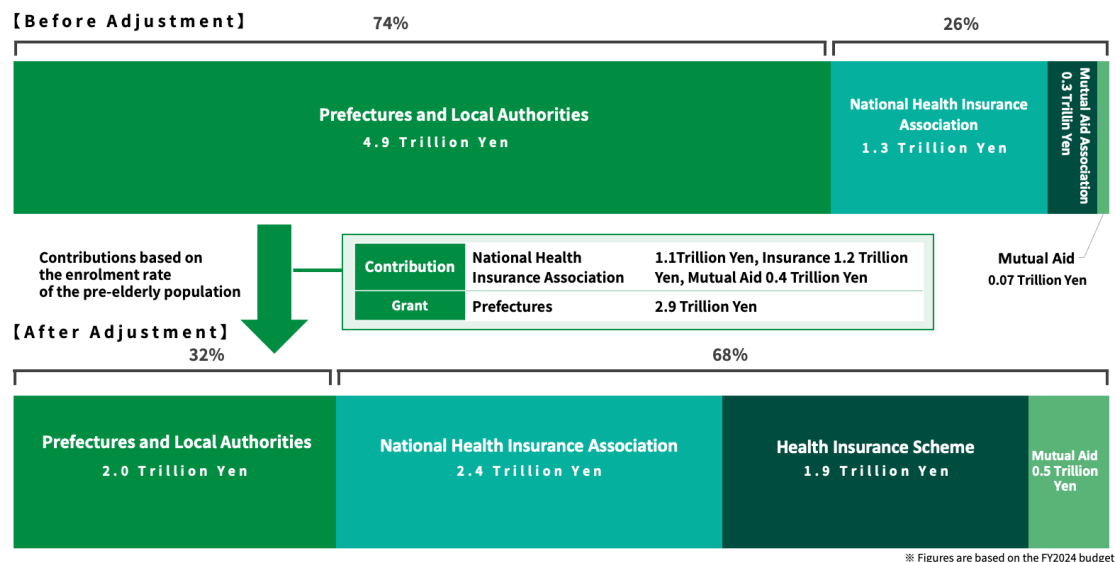
Structure of the Elderly Healthcare System

The structure of healthcare for older people is complex. This is because it deviates significantly from the basic insurance principle whereby premium income and insurance benefits are balanced, relying instead on financial support from other medical insurance schemes. Older people constitute a vulnerable group with high disease risk but relatively low-income levels; therefore, by accepting financial support from the working-age population, the system forms part of a broader social security framework in which society as a whole ensures access to healthcare. Separate systems are implemented for the “young-old” (aged 65–74) and the “old-old” (aged 75 and over).

The financial adjustment mechanism for the young-old is designed to correct imbalances in the burden borne by insurers that arise from the uneven distribution of individuals aged 65–74 across insurance schemes. Contributions are adjusted according to each insurer’s proportion of young-old enrollees. As a result, unlike the system for the old-old, individuals aged 65–74 remain members of their respective health insurance schemes.⁸⁶ As shown in Figure 3-1-2, prior to the introduction of this financial adjustment, more than 70% of healthcare benefit costs for the young-old were borne by municipal National Health Insurance schemes and similar insurers, with the remaining insurers covering just under 30%. Following the implementation of financial adjustment, these inter-insurer imbalances are corrected, resulting in a cost-sharing structure in which approximately 30% of young-old benefit costs are borne by municipal National Health Insurance schemes and around 70% by other insurers.

⁸⁶ Ministry of Health, Labour and Welfare. *Medical Insurance in Japan*.
http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuhoken/iryuhoken01/index.html

Figure 3-1-2 Comparison of the Proportion of Funding for the Medical Care System for the Elderly Before and After Adjustment



Funding Sources of the Late-Stage Elderly Healthcare System

As shown in Figure 3-1-3, the funding sources of the Late-Stage Elderly Medical Care System consist of approximately 50% public funding (national government: prefectures: municipalities = 4:1:1), around 40% support contributions from each insurer, namely, insurance premiums paid by the working-age population, and roughly 10% insurance premiums paid by older persons themselves. The scale of medical expenditure for the late-stage elderly amounts to a total of ¥18 trillion in FY2022, comprising ¥16.5 trillion in benefit payments and ¥1.5 trillion in patient out-of-pocket payments.^{87,88}

In principle, the support contributions financed by insurance premiums from the working-age population are apportioned based on the number of enrollees (aged 0–74) covered by each insurer. As this allocation is determined solely by enrollee numbers, it imposes a particularly heavy burden on insurers with weaker financial capacity. To ensure that cost-sharing better reflects the ability to pay, the allocation method among employee-based insurers has been gradually revised through the introduction of a “total remuneration-based” approach. Specifically, the proportion based on total remuneration was increased to one-half in FY2015, to two-thirds in FY2016, and has been fully based on total remuneration since FY2017.⁸⁹

⁸⁷ Ministry of Health, Labour and Welfare. *About Japan's Medical Insurance System*.

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html

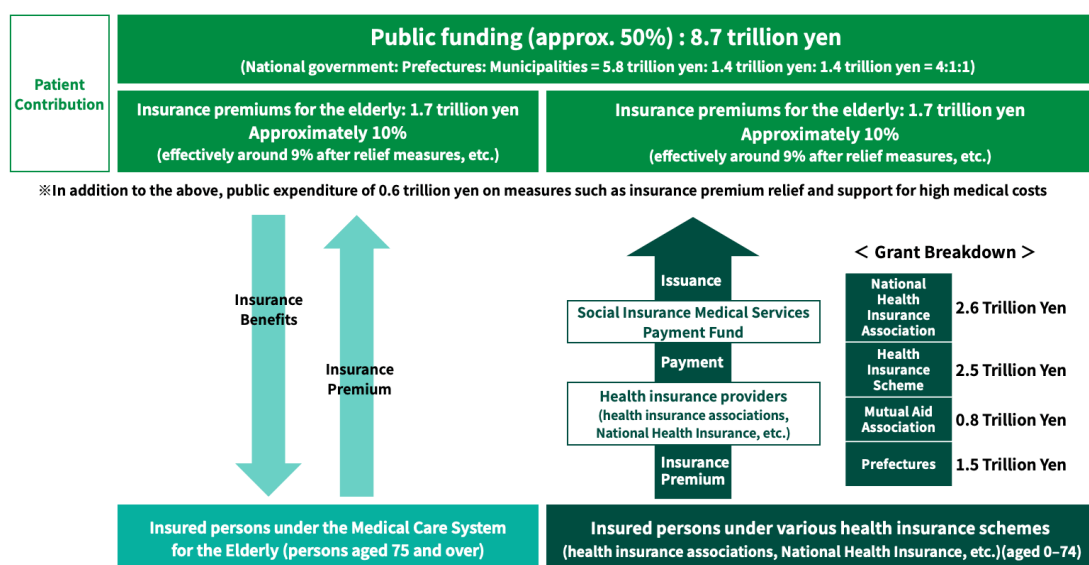
⁸⁸ Ministry of Health, Labour and Welfare. *Basic Materials on Medical Insurance — Status of Medical Expenditure, FY2022*.

https://www.mhlw.go.jp/content/kiso_r04.pdf

⁸⁹ Ministry of Health, Labour and Welfare. *Cost Sharing (Total Remuneration-Based Contribution)*.

http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutokatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000140159.pdf

Figure 3-1-3 The Structure and Budget of the Medical Care System for the Elderly



The Structure of Insured Medical Care in Japan

This section explains the mechanism through which medical expenses are paid when insured persons receive care at medical institutions, focusing on the structure of insured medical care in Japan.

As a prerequisite for this system, Japan operates a medical fee schedule system. Medical fees refer to the remuneration received by insured medical institutions and insured pharmacies as compensation for medical services and pharmaceuticals provided within the scope of public health insurance coverage.⁹⁰ Insured medical institutions and pharmacies submit claims to the claims review and payment organizations for the total amount calculated on a fee-for-service basis, excluding the patient's out-of-pocket contribution. As noted in Section 2, medical fees are determined by the Minister of Health, Labour and Welfare based on deliberations by the Central Social Insurance Medical Council (Chuikyo) and are revised once every two years. Medical fees are expressed in points, with one point valued at ¥10.

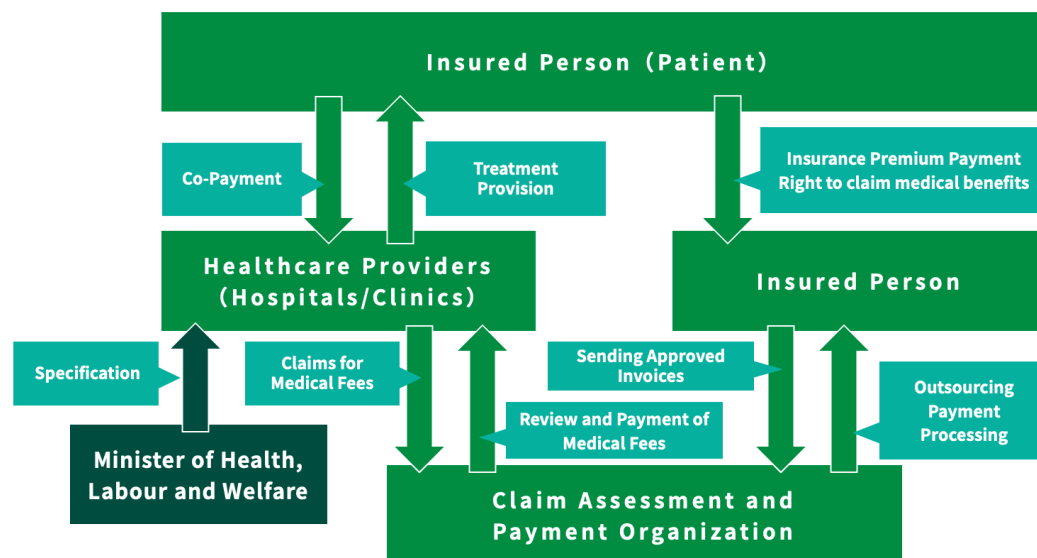
The flow of insured medical care is illustrated in Figure 3-1-4. When an insured person visits a medical institution, they pay the out-of-pocket portion of the medical costs for the services received directly to the institution at the point of care. The remaining 70–90% of the medical costs, after deducting the patient's share, are claimed by the medical institution from the insurer. However, in practice the process of submitting medical fee claims is both large in volume and highly specialized. Consequently, this task is delegated to specialized organizations known as claims review and payment bodies, namely the Social Insurance Medical Fee Payment Fund (hereafter, the Payment Fund) and the National Health Insurance Federation (hereafter, NHI Federation).

These claims review and payment bodies examine the appropriateness of the submitted claims, request payment of the approved medical fees from the medical insurers, receive the payments from

⁹⁰ Ministry of Health, Labour and Welfare. *About the Medical Fee Schedule System*.
<http://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01b.pdf>

the insurers, and subsequently disburse the medical fees to the medical institutions. In other words, their role is to review the medical fee statements (receipts) submitted by medical institutions and, based on the results of this review, to carry out the payment of medical fees.

Figure 3-1-4 The Process of Insured Medical Treatment



Claims Review and Payment Organizations

Claims review and payment organizations established in each prefecture are responsible for tasks such as transmitting claims to insurers and processing medical fee claims submitted by medical institutions. The term “processing” is used here because, in principle, the review and payment of medical fee claims is a function that insurers themselves should perform. Under the original framework, insured medical institutions that provide services to patients submit claims for medical fees directly to insurers after delivering care, and claims review and payment constitute one of the core functions of insurers.

However, in order to ensure the smooth and efficient payment of medical fees, the Social Insurance Medical Fee Payment Fund and the National Health Insurance Federation were established on a prefectural basis, and a system has been adopted whereby the administrative tasks related to the payment of medical fees are delegated to these organizations.

The purpose of the review conducted by claims review and payment organizations is to verify whether the medical services provided by medical institutions to individual patients comply with the regulations governing insured medical care, including the Rules for Medical Care for the Insured and related notifications. Although such reviews are, in principle, conducted in accordance with a single national set of regulations, disparities between branches, referred to as “inter-branch variation”, have been identified as an ongoing issue, whereby the criteria used to assess the appropriateness of claims differ across regional branches.⁹¹

⁹¹ Ministry of Health, Labour and Welfare. *Outline of the Plan for Enhancing Efficiency and Sophistication of the Claims Payment Fund's Operations*.
<http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000169999.pdf>

3.2 Medical Insurance System | Japan's Long-Term Care Insurance

System

Overview of the Long-Term Care Insurance System

Japan's Long-Term Care Insurance (LTCI) system is a social insurance scheme designed to support long-term care for the elderly through collective societal responsibility. It was introduced in 2000 and is administered by municipalities, which serve as the insurers. All residents aged 40 and over are insured under the system. As of April 2024, more than 6.6 million people were receiving services under the LTCI scheme.⁹²

Background to the Establishment of the Long-Term Care Insurance System

Under the previous elderly welfare system, municipalities were the primary decision-makers regarding service provision. As a result, users were unable to choose services freely, and service content tended to be standardized (the so-called “placement-based system”). In addition, service utilization was subject to means-based contributions, which imposed a heavy burden on middle- and high-income groups, and long-term hospitalization in general hospitals for care-related reasons became a serious issue. Furthermore, the division of elderly care into separate systems for elderly welfare and elderly medical care also resulted in structural problems.

With the progression of population ageing, care needs increased significantly due to a growing number of older persons requiring care and the lengthening of care periods. At the same time, changes in family structures, such as the rise of nuclear families and the ageing of family caregivers, altered the circumstances surrounding families that had traditionally supported older persons in need of care.⁹³ In light of these issues inherent in the former elderly welfare and medical care systems, the Long-Term Care Insurance system was established as a mechanism through which society as a whole shares responsibility for supporting long-term care for older persons.

Fundamental Principles of the Long-Term Care Insurance System

- **Support for independence:** Going beyond the provision of assistance with daily activities, the system aims to support the independence of older persons.
- **User-centered approach:** Users are able to choose and receive comprehensive health, medical, and welfare services from a diverse range of providers.
- **Social insurance model:** The system adopts a social insurance framework in which the relationship between benefits and contributions is clearly defined.

⁹² Ministry of Health, Labour and Welfare. *Summary of the FY2023 Survey on Long-Term Care Benefit Expenditure*. <https://www.mhlw.go.jp/toukei/saikin/hw/kaigo/kyufu/23/dl/11.pdf>

⁹³ Ministry of Health, Labour and Welfare. *The Current Status and Future Role of the Public Long-Term Care Insurance System*. http://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/201602kaigohokenntoha_2.pdf

Insured Persons and Premiums

Insured persons under the LTCI system are divided into two categories: those aged 65 and over (Category I insured persons), and those aged 40 to 64 who are enrolled in a medical insurance scheme (Category II insured persons).

- **Category I insured persons:** Individuals aged 65 and over are eligible to receive long-term care services upon being certified as requiring long-term care or support, regardless of the underlying cause.
- **Category II insured persons:** Individuals aged 40 to 64 are eligible to receive services only when they are certified as requiring long-term care or support due to age-related diseases (specified diseases).

As of March 2023, the number of Category I insured persons stood at 35.85 million, while the monthly average number of Category II insured persons during fiscal year 2021 was 41.85 million.^{94,95}

Premiums for Category I insured persons (aged 65 and over) are paid separately from medical insurance premiums. Premium levels are determined by each insurer (municipality) based on medium-term projections of service demand over a three-year period. At present, premiums are structured across 13 standard income-based tiers.⁹⁶ Premiums for Category II insured persons (aged 40 to 64) are collected together with medical insurance premiums, with rates set by the respective medical insurers.⁹⁷

The rationale for setting the lower age threshold for LTCI coverage at 40 was the subject of considerable debate at the time of the system's establishment. Proposals included limiting coverage to those aged 65 and over or extending it to those aged 20 and over. However, the 1996 outline proposal for the Long-Term Care Insurance system submitted to the Council on Health and Welfare for the Elderly argued that individuals aged 40 and over are more likely to require social support through long-term care insurance as family members caring for their parents. On this basis, it was decided that persons aged 40 and over should be insured, with care costs shared through social solidarity. These discussions ultimately shaped the current framework of the LTCI system.

Financing of the Long-Term Care Insurance System

As shown in Figure 3-2-1, the LTCI system is financed equally by insurance premiums (50%) and public funding (50%). Under the draft budget for fiscal year 2024, total long-term care benefit expenditure amounts to ¥13.2 trillion. This comprises ¥3.0 trillion from Category I insured persons, ¥3.6 trillion from Category II insured persons, ¥3.1 trillion in national government contributions, ¥1.9 trillion in

⁹⁴ Ministry of Health, Labour and Welfare. *Summary of the FY2022 Annual Report on Long-Term Care Insurance Services*. https://www.mhlw.go.jp/topics/kaigo/osirase/jigyoy22/dl/r04_gaiyou.pdf

⁹⁵ Ministry of Health, Labour and Welfare. *About Long-Term Care Insurance Premiums for Category II Insured Persons*. https://www.mhlw.go.jp/topics/kaigo/osirase/jigyoy21/dl/r03_hihokensha.pdf

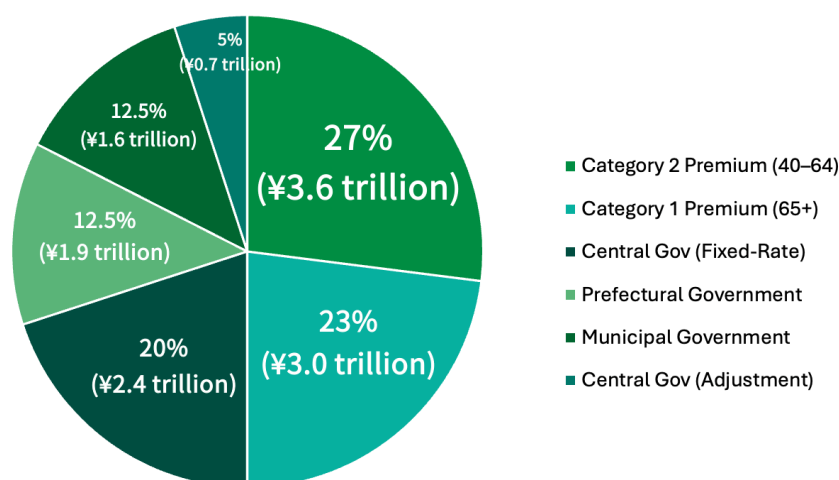
⁹⁶ Ministry of Health, Labour and Welfare. *On Benefits and Cost Sharing*. <https://www.mhlw.go.jp/content/12300000/001182065.pdf>

⁹⁷ Ministry of Health, Labour and Welfare. *About the Long-Term Care Insurance System*. http://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/2gou_leaflet.pdf

prefectural contributions, and ¥1.6 trillion in municipal contributions.

As with medical expenditure, long-term care benefit expenditure has continued to reach record highs each year. It is expected to increase further in the future as population ageing progresses.⁹⁸

Figure 3-2-1 The Composition and Scale of Long-Term Care Insurance Funding



Note: The proportions of Category 1 and Category 2 insurance premiums are apportioned according to population for each three-year Long-Term Care Insurance business plan period. Central government subsidies are allocated on an adjusted basis according to factors such as the proportion of Category 1 insured persons aged 75 or over and the distribution of income brackets.

Source: Ministry of Health, Labour and Welfare, 'How the System Works (Long-Term Care Insurance Finances)' <https://www.mhlw.go.jp/content/zaiseinoshikumi.pdf>

Fiscal measures are also in place to address disparities in financial burden. Specifically, fiscal adjustment is carried out using 5% of the national government contribution (which accounts for 26% in total) to offset both the increase in benefit expenditure resulting from a high proportion of late-stage elderly persons and the decrease in revenue resulting from the lower income levels of insured persons. Through this mechanism, disparities in fiscal capacity among municipalities are mitigated. In this respect, the fiscal adjustment framework resembles the inter-insurer fiscal adjustment mechanism in the elderly medical care system described in Section 1.2, in that both systems are designed to correct differences in “fiscal capacity” among insurers.

Use of Long-Term Care Services and Certification of Care Needs

In order to use long-term care services, individuals must apply at a municipal office or a Community General Support Center and obtain certification indicating the need for care, known as “support need certification” or “care need certification.” Once certified, a care manager formulates a care plan, enabling the individual to receive a range of long-term care services covered by long-term care insurance.

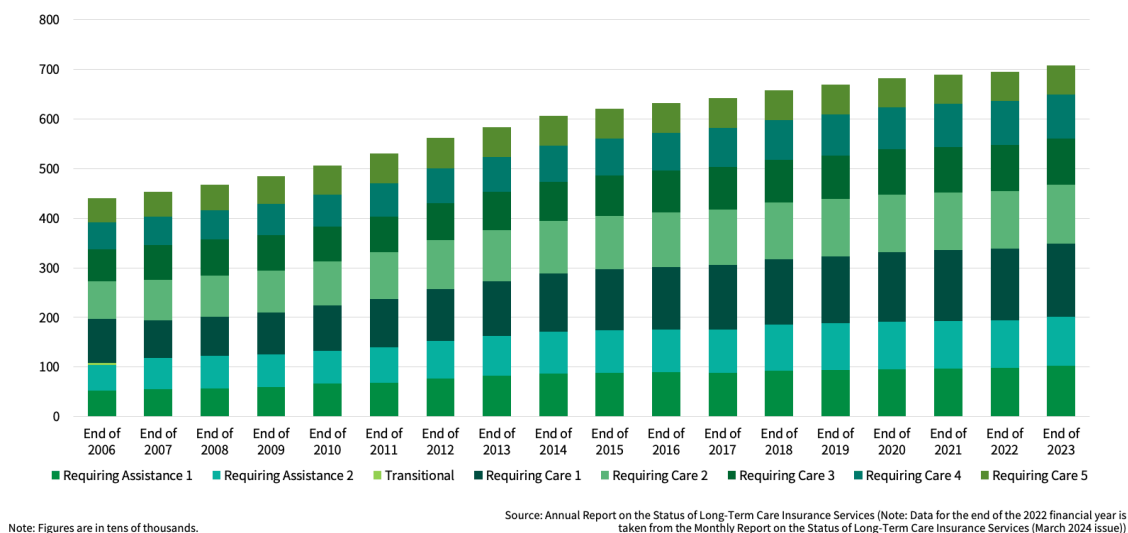
Certification is determined by an expert committee based on a survey comprising 74 items related to activities of daily living, as well as a medical certificate provided by healthcare professionals. The level of care need is classified into one of seven categories: Support Level 1 or 2, or Care Level 1 through 5. The certification period is, in principle, six months for initial certification and twelve months for

⁹⁸ Ministry of Health, Labour and Welfare. *Trends in Total Long-Term Care Insurance Expenditure*. <https://www.mhlw.go.jp/content/zaiseinoshikumi.pdf>

renewals. Reassessments may be conducted at any time if the individual's condition deteriorates.⁹⁹ Annual trends in the number of certified persons requiring care are shown in Figure 3-2-2.

In the 2006 revision of the Long-Term Care Insurance Act, preventive care services were newly introduced in response to the continuous increase in the number of insured persons certified as having mild care needs (Support Level or Care Level 1), which had not led to improvements in care dependency. At that time, individuals previously certified as Care Level 1 were reassessed and reclassified as either “Care Level 1” or “Support Level 2,” depending on the potential for maintaining or improving their condition. This classification framework has remained in place to the present day.

Figure 3-2-2 Annual Trends in the Number of People Certified as Requiring Support or Care



3.3 Medical Insurance System | Private Health Insurance

The Role of Private Health Insurance under the Universal Health Insurance System

In Japan, the scope of benefits covered by the public health insurance system is broad, and patients enjoy free access to medical institutions. As a result, private health insurance primarily serves a supplementary role to the public medical insurance system. Owing to factors such as the High-Cost Medical Expense Benefit System and the prohibition of mixed billing,¹⁰⁰ The role played by private

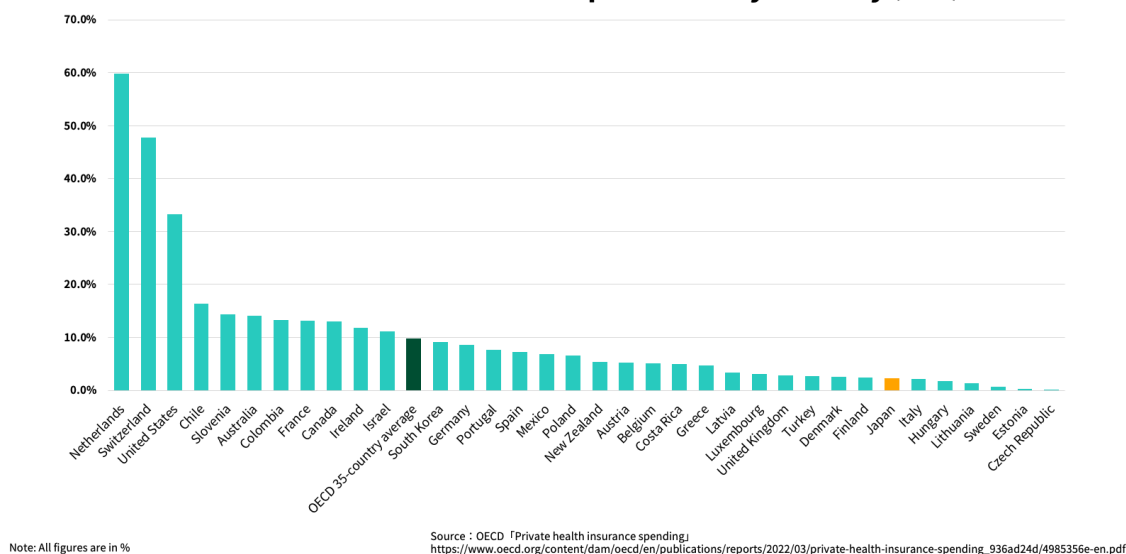
⁹⁹ Ministry of Health, Labour and Welfare. *About the Long-Term Care Insurance System*. www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/2gou_leaflet.pdf.

¹⁰⁰ In Japan, mixed medical treatment (混合診療) refers to receiving both insurance-covered care (*hoken shinryo*, 保険診療) and non-insurance-covered care (*jiyu shinryo*, 自由診療) at the same time. Under the principle of non-coverage for mixed treatment (混合診療保険適用外原則), mixed treatment is generally prohibited. As a result, patients usually cannot combine insured and uninsured services in a single episode of care.

However, since 2006 the system of insured–uninsured combined medical expenses (保険外併用療養費制度) has been established. Under this system, certain advanced medical services that are not yet covered by public insurance but are intended for future inclusion may be provided alongside insured treatment under specific rules. For such cases, where safety and effectiveness have been confirmed according to prescribed criteria, limited combinations of insured and uninsured services are permitted. This mechanism allows experiments with advanced care options before formal insurance coverage is established.

health insurance remains limited compared with that in other countries. The share of private health expenditure in Japan stands at 2.3%, placing it among the lowest levels within OECD countries (Figure 3-3-1).¹⁰¹

Figure 3-3-1 Share of Private Healthcare Expenditure in Total Current Healthcare Expenditure by Country (2019)



The current size of Japan's private health insurance market is approximately JPY 7 trillion (JPY 7.2 trillion as of 2023) and has been increasing steadily year by year.¹⁰² In concrete terms, private health insurance primarily provides coverage for services that fall outside the scope of public insurance benefits, compensation for ancillary expenses incurred at the time of illness, and income protection in the event of work absence.^{103,104,105}

At the same time, changes in disease patterns, the growing emphasis on cancer care,¹⁰⁶ and the expansion of advanced medical treatments have led to shifts in demand for private health insurance. Furthermore, against the backdrop of a declining birth rate, population ageing, technological innovation, and relatively low levels of out-of-pocket payments, national healthcare expenditure has continued to rise annually. This has raised the possibility that the scope of public health insurance

¹⁰¹ OECD. *Private Health Insurance Spending*.

https://www.oecd.org/content/dam/oecd/en/publications/reports/2022/03/private-health-insurance-spending_936ad24d/4985356e-en.pdf

¹⁰² Life Insurance Association of Japan. *Trends in Life Insurance 2024 Edition*.

https://www.seiho.or.jp/data/statistics/trend/pdf/all_2024.pdf

¹⁰³ Tajika, Eiji & Kikuchi, Jun. *The Roles of Government and Private Insurance in Medical Coverage: Theoretical Frameworks and International Case Studies*.

http://www.mof.go.jp/pri/publication/financial_review/fr_list6/r111/r111_02.pdf

¹⁰⁴ Nakahama, Takashi. *The Role of Private Medical Insurance: A Comparison between Japan and the United States*.

https://www.istage.ist.go.jp/article/isis/2007/596/2007_596_596_69/.pdf

¹⁰⁵ When a taxpayer pays premiums for life insurance, long-term care and medical insurance, or individual annuity insurance, they are eligible for a deduction from taxable income. This is known as the life insurance premium deduction, and it reduces the burden of both income tax and resident tax in proportion to the amount of insurance premiums paid.

¹⁰⁶ Since 1981, cancer has ranked as the leading cause of death in Japan. According to the cause-specific mortality figures for 2022, cancer had the highest mortality rate at 316.1 deaths per 100,000 population, followed by heart disease at 190.8, and senility at 147.1. For further details, see: *Summary of the 2022 Vital Statistics Monthly Report (Annual Total, Preliminary Figures)*.

<https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/geppo/nengai22/dl/gaikyouR4.pdf>

coverage may be revised, with potential modifications or reductions in covered services. In light of these developments, the future role of private health insurance is likely to evolve in response to the direction and substance of reforms to the public health insurance system.^{107,108} While most private health insurance products currently available on the market provide limited, standardized, lump-sum monetary benefits, the role of private insurance in covering medical services outside the scope of public insurance may expand in the future.

Background to the Rapid Growth of the Private Health Insurance Sector

In the post-war period, Japan's private insurance industry operated under extensive government regulation, resulting in uniform insurance products and business practices (the so-called "convoy system"). However, as trade liberalization with other countries progressed from the 1960s onwards, the insurance sector also came under pressure to allow market entry by foreign insurers. Consequently, in the early 1970s, the life insurance market was partially liberalized, limited to so-called "third-sector insurance", including medical and cancer insurance, which at the time were relatively underdeveloped domestically. As a result, the third-sector insurance market¹⁰⁹ came to be dominated by foreign insurers. Following a comprehensive revision of the Insurance Business Act in 1995, the full liberalization of the third-sector insurance market in 2001 allowed all domestic insurance companies to enter this field.¹¹⁰ Thereafter, the third-sector insurance market expanded rapidly over a short period and has since become one of the most highly competitive segments of the insurance industry. In recent years, new types of products known as "simplified underwriting health insurance" have emerged, targeting individuals with pre-existing conditions or medical histories who previously found it difficult to obtain coverage. These products have enabled middle-aged and older individuals with health conditions to prepare for the financial risks associated with hospitalization and surgery. In addition to diversification in insurance products, sales channels have also expanded, with the increased use of online distribution methods and the deregulation of sales through banks and securities companies. More recently, in response to medium- to long-term demographic changes and increasingly diverse consumer needs, insurers have strengthened their business activities not only in traditional insurance domains but also in related areas such as long-term care and healthcare services.¹¹¹

Against this background, the number of in-force private health insurance contracts has continued to increase annually. In 2023, the number of health insurance policies providing coverage for

¹⁰⁷ Nakahama, Takashi. *The Role of Private Medical Insurance: A Comparison between Japan and the United States*.

https://www.istage.jst.go.jp/article/jst/2007/596/2007_596_596_69/.pdf

¹⁰⁸ Kawaguchi, Hiroyuki. *International Comparison of Public Medical Security Systems and Private Medical Insurance: Division of Roles between Public and Private Financing and Their Functions*.

<http://www.seijo.ac.jp/pdf/faeco/kenkyu/196/196-kawaguchi.pdf>

¹⁰⁹ In Japan, insurance can broadly be classified into three categories: life insurance, non-life (property and casualty) insurance, and third-sector insurance. Third-sector insurance refers to a group of insurance products—such as medical insurance or cancer insurance—that do not fall under either life insurance or non-life insurance. (See: Nobuko Serizawa. *The Third-Sector Insurance Market*.)

¹¹⁰ Serizawa, Nobuko. *The Third-Sector Insurance Market*.

http://dspace.lib.niigata-u.ac.jp/dspace/bitstream/10191/16657/1/90_249-271.pdf

¹¹¹ Financial Services Agency. *2024 Insurance Monitoring Report*.

<https://www.fsa.go.jp/news/r6/hoken/20240703/02.pdf>

hospitalization and surgical procedures under the main contracts of all life insurance companies reached 44.92 million.¹¹²

¹¹² Life Insurance Association of Japan. *Trends in Life Insurance 2024 Edition*.
https://www.seiho.or.jp/data/statistics/trend/pdf/all_2024.pdf

Japanese Health Policy

4. Healthcare Delivery System

September 2026

4.1 Healthcare Delivery System | Overview of Japan's Healthcare

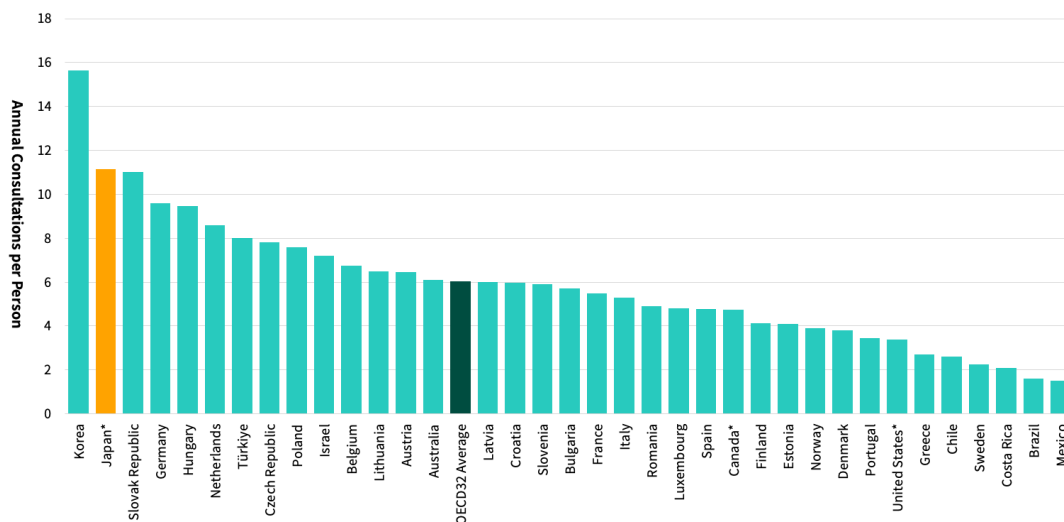
Delivery System

International Comparison of Japan's Healthcare Delivery System

A defining characteristic of Japan's healthcare delivery system is its large scale. Looking at consultation frequency as an indicator of the scale of outpatient care, as of 2021 the average number of visits per person was 11.1 per year, the second highest among OECD countries after South Korea.

With regard to inpatient care, the discharge rate, which indicates the frequency of hospital admissions, places Japan around the middle among OECD countries and does not appear particularly high. However, the average length of hospital stay is exceptionally long, exceedingly more than twice that of South Korea, which ranks second. Consequently, the overall scale of inpatient care provided in Japan can also be considered very large.

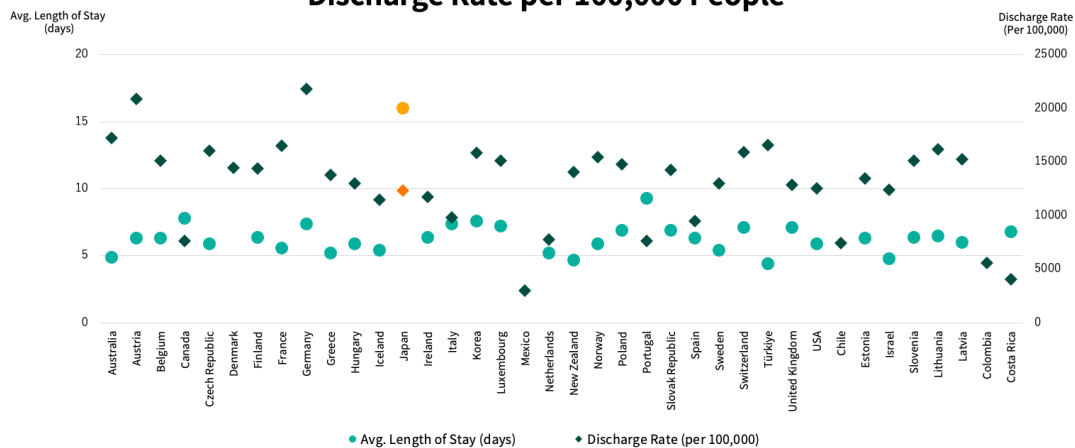
Figure 4-1-1 Average Number of Face-to-face Consultations Per Person (2021)



Note: For countries marked with an asterisk (*), data from 2020 has been used.

Source : OECD Health Statistics 2023.

Figure 4-1-2 International Comparison of Average Length of Stay and Discharge Rate per 100,000 People

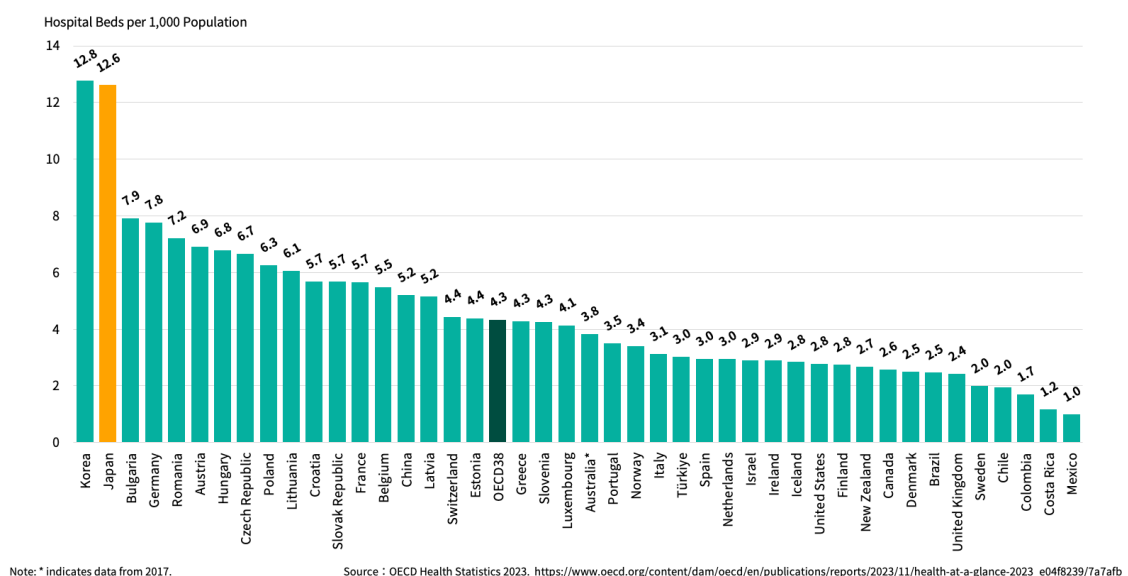


Note 1: Regarding the average length of stay, the category refers to conditions falling under 'curative care'; this is calculated by dividing the total number of days spent in hospital by all inpatients over a one-year period by the number of admissions or discharges. Day-case patients are excluded. Figures are shown for both all acute care cases and deliveries without complications.
 Note 2: Regarding average length of stay, figures for 2021 are used, although figures for 2020 are used for Germany and Switzerland, and figures for 2017 are used for Greece. No data is available for Denmark, Mexico, Chile and Colombia.
 Note 3: Regarding discharge rates, the category refers to the discharge rate for conditions falling under 'all causes'.
 Note 4: Although figures from 2021 are used, data from 2020 is used for Japan; 2018 for Turkey and the United Kingdom; 2017 for Iceland and Greece; 2016 for Luxembourg and Denmark; and 2010 for the United States.
 Source : OECD "Length of hospital rate", "Hospital discharge rates"

Reflecting the large scale of inpatient medical service provision, Japan has a high number of hospital beds per capita. As of 2021, there were 12.6 beds per 1,000 population, a level that stands out as exceptionally high alongside South Korea.

By contrast, the number of places in long-term care facilities relative to the elderly population is limited. In 2021, there were 34.5 beds per 1,000 people aged 65 and over, which can be considered slightly below the OECD average.

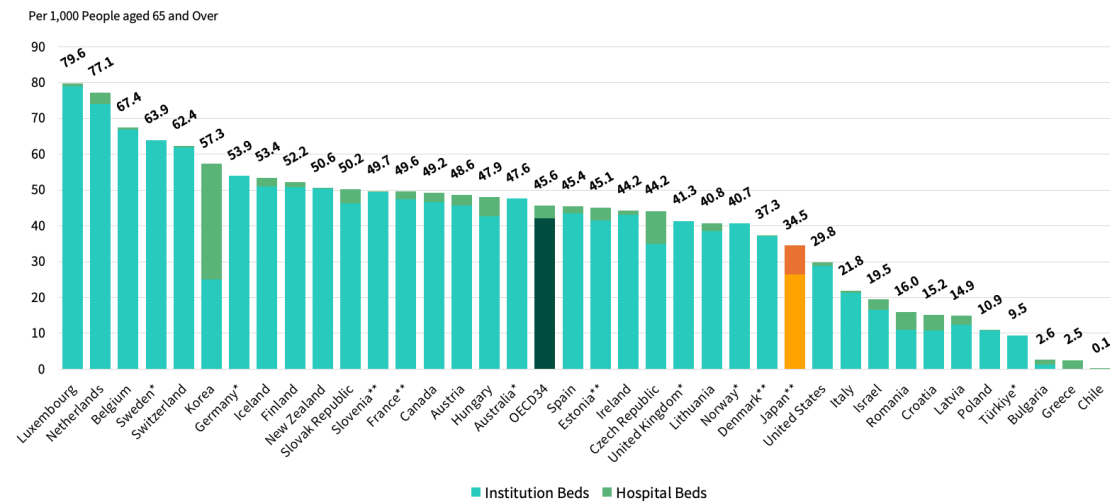
Figure 4-1-3 Number of hospital beds per 1,000 people (2021)



Note: * indicates data from 2017.

Source : OECD Health Statistics 2023. https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/11/health-at-a-glance-2023_e04f8239/7a7afb

Figure 4-1-4 Number of Long-term Care Beds in Care Homes and Hospitals (2021)



Note 1: Data for Iceland is from 2020.

Note 2: For countries marked with *, data on the number of long-term care beds in hospitals is not available.

Note 3: For countries marked with **, the number of long-term care beds in hospitals excludes psychiatric beds.

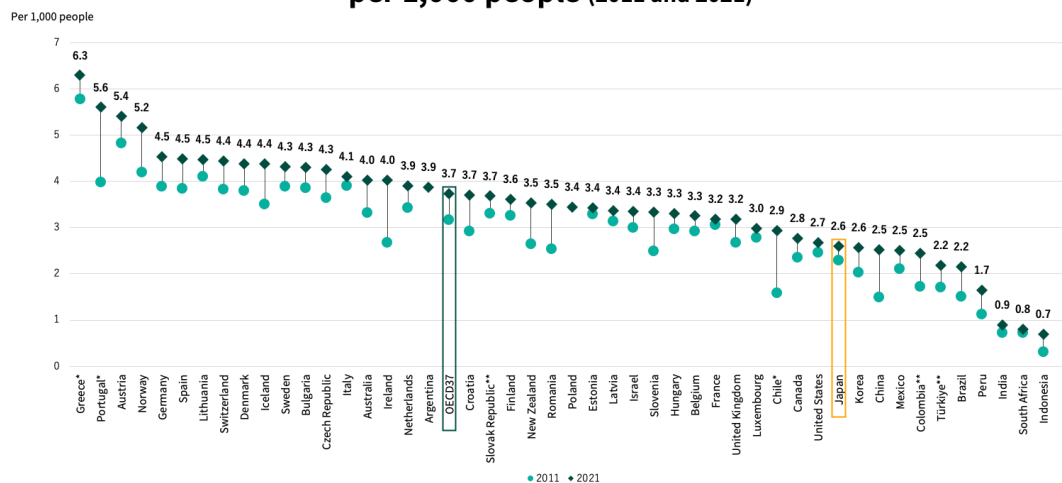
Source : OECD Health Statistics 2023

https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/11/health-at-a-glance-2023_e04f8239/7a7af635-en.pdf

Despite the large scale of medical service provision, the number of physicians in Japan is relatively low. With 2.6 physicians per 1,000 population, Japan belongs to the lower group among OECD countries. However, in domestic policy debates, future population decline is expected to lead to an oversupply of physicians, and therefore a substantial increase in the number of doctors is not actively being considered. Instead, policy discussions focus on the efficient allocation of physicians at the micro level, particularly across regions and medical specialties.

By contrast, when compared with other OECD countries, Japan has relatively high numbers of pharmacists and nurses.

Figure 4-1-5 International comparison of the number of clinical doctors per 1,000 people (2011 and 2021)



Note 1: In countries marked with an asterisk (*), the figures include all doctors holding a medical license; consequently, the number of doctors actually practicing is significantly overestimated (e.g. in Portugal, the overestimation is approximately 30%).

Note 2: In countries marked with **, the figures include not only doctors providing direct patient care but also those working in managerial, educational or research roles within the healthcare sector (this adds a further 5–10 per cent to the total).

Note 3: The data for Luxembourg is from 2017.

Source : OECD Health Statistics 2023.

Figure 4-1-6 International Comparison of the Number of Clinical Nurses per 1,000 People (2011 and 2021)

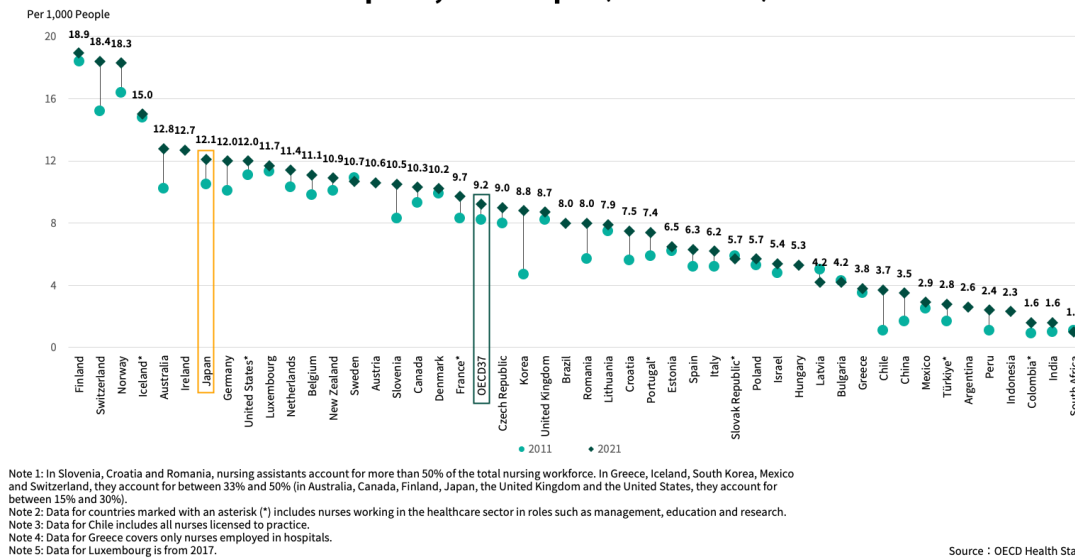
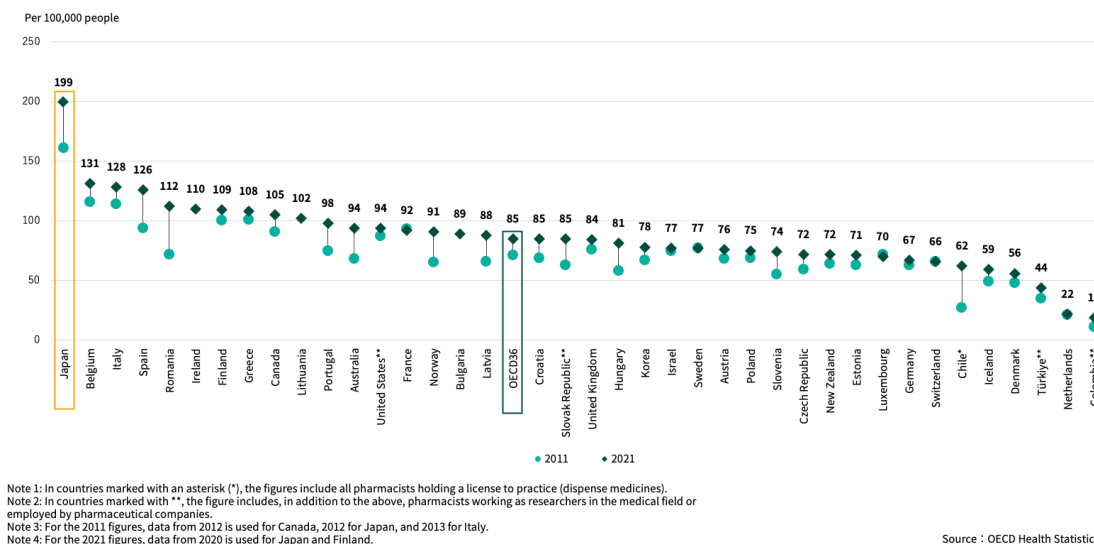


Figure 4-1-7 International Comparison of the Number of Clinical Pharmacists per 100,000 People (2011 and 2021)



Healthcare Delivery System Oriented towards the Private Sector

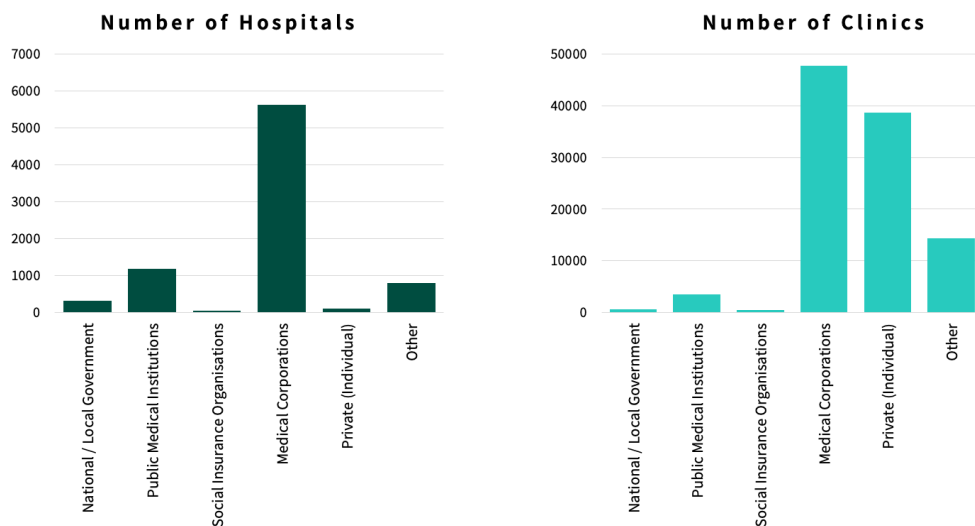
The characteristics of Japan's healthcare delivery system described above can largely be explained by the prominent role played by the private sector.¹¹³ A substantial proportion of outpatient care is provided within the private sector, which also accounts for a large share of hospital beds, and is associated with a tendency towards longer average lengths of hospital stay. It should be noted that the term "private sector" as used here does not refer to for-profit enterprises, but rather to privately

¹¹³ In this report, medical institutions established and operated by medical corporations or individual practitioners are classified as belonging to the private sector. Although a limited number of medical institutions established by for-profit enterprises exist due to historical circumstances, the establishment of medical institutions for commercial purposes is currently highly restricted.

operated medical corporations that are not publicly owned.

First, it is important to confirm that the private sector is larger in scale than the public sector.¹¹⁴ In terms of the number of medical institutions, the private sector accounts for more than 70 per cent of hospitals and approximately 82 per cent of clinics (Figure 4-1-8). When measured by the number of beds, the private sector accounts for around 57 per cent of hospital beds and approximately 93 per cent of clinic beds (Figure 4-1-9). This structural configuration is widely regarded as one of the defining characteristics of Japan's healthcare delivery system.¹¹⁵

Figure 4-1-8 Number of Hospitals and Clinics by Operator (2024)



Source : Overview of the 2024 Survey of Medical Facilities (Operational Status)

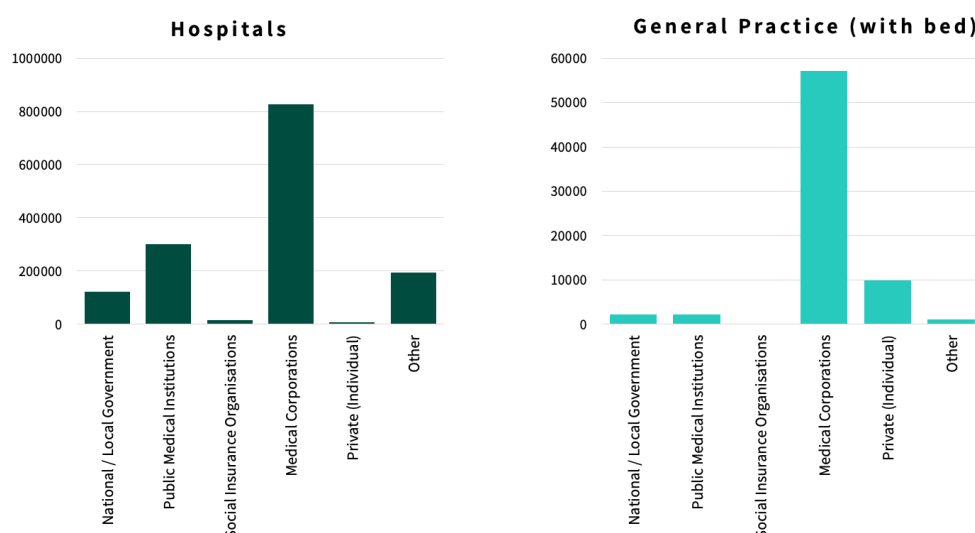
¹¹⁴ Ministry of Health, Labour and Welfare. *The Current Status and Challenges of the Healthcare Delivery System*.

http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000184301.pdf

¹¹⁵ Ministry of Health, Labour and Welfare. *Survey and Research Report on the Actual Conditions of Medical Corporations Overseas*.

http://www.mhlw.go.jp/file/06-Seisakujouhou-10800000-Iseikyoku/001_2.pdf

Figure 4-1-9 Number of Beds by Provider (2024)



Source: Overview of the 2024 Survey of Medical Facilities (Operational Status)

In the provision of outpatient care as well, the private sector accounts for a substantial share. Approximately 57.3 per cent of outpatient expenditure is attributable to clinics,¹¹⁶ while of the remaining share provided by hospitals, around 41 per cent is accounted for by the private sector.

Table 4-1-1 Medical Expenses for In-Patient and Out-Patient Care (2023)

(Trillion Yen)

	In-Patient	Out-Patient
Doctor	18.7(99.6%)	16.4(59%)
Hospital	18.4	7
University	2.3	1.29
Public	6.4	2.84
Private Sector	9.8	2.87
Clinic	0.29	9.4
Dentist	0.075(0.39%)	3.22(12%)
Pharmacy		8.31(30%)

Note 1: This includes the costs of dietary care and daily living care during hospitalization. Medical expenses are included under 'Medical Inpatient Care', and dental expenses under 'Dental Inpatient Care'.

Note 2: 'University hospitals' refers to medical institutions that are educational institutions for medical training.

Note 3: 'Public hospitals' refers to medical institutions established by the State (including independent administrative agencies), public medical institutions (prefectures, municipalities, etc.) and medical institutions established by social insurance-related organizations (health insurance associations and their federations, etc.). However, this excludes educational institutions for medical training.

Note 4: 'Private hospitals' include medical institutions established by corporations and individuals.

Note 5: The figures in parentheses indicate the approximate percentage of the total for inpatients and outpatients respectively.

Source : Trends in Medical Expenditure for the 2024 Financial Year

Despite an overall trend towards shorter average lengths of hospital stay, sectoral analysis reveals that this trend has been more modest within the private sector, and in some cases has even shifted towards longer stays.

¹¹⁶ Strictly speaking, not all clinics are operated by private entities; however, it is generally considered that the majority are privately run.

Free Access

Japan's system of healthcare access is generally regarded as being of a high standard. A key mechanism underpinning this accessibility is the principle of free access, which allows individuals to choose and consult medical institutions freely, based on their own judgement. The vast majority of healthcare providers in Japan are registered as service providers under the public health insurance system, and insured individuals are therefore able to receive necessary medical services with a fixed level of cost-sharing.¹¹⁷

As a result, waiting times for outpatient consultations are relatively short. The largest proportion of patients (27.9 per cent) report waiting less than 15 minutes, followed by those waiting between 15 and 30 minutes (24.9 per cent), and between 30 minutes and one hour (20.6 per cent). In total, approximately 70 per cent of patients are seen within one hour. Similarly, the interval between being diagnosed as requiring hospitalization and actual admission is short: 70.3 per cent of inpatients are admitted within one week, while a further 23.1 per cent are admitted within one week to one month, together accounting for over 80 per cent of cases.¹¹⁸

**Table 4-1-2 Reasons for Delays in Hospital Admission
by Length of Time Prior to Admission (%)**

	Total	No Beds Available	No Appointments for Surgery or Checkups	Personal or Family Circumstances	Financial Reasons	Others	Unknown	Unspecified
Total	100	15.1	20.6	21.7	1.2	21.5	10.8	9.1
Less than 1 week	70.3	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
1 week to less than a month	23.1	4.11	3.93	4.76	0.3	4.85	2.86	2.31
More than a month	14.3	1.56	3.76	3.36	0.16	3.19	1.19	1.09
Do not remember	4.3	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Unspecified	5.5	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.

Note: The figure for 'less than one week' includes emergency admissions and ambulance transfers.

Source: Ministry of Health, Labour and Welfare, '2023 Survey on Healthcare Utilisation'

In recent years, however, concerns have been raised regarding the unintended consequences of the free access system, particularly the tendency towards excessive or unnecessary healthcare utilization. It has been suggested that outpatient demand has become concentrated in certain hospitals, giving rise to challenges such as longer waiting times for patients and an increased outpatient workload for hospital-based physicians. One frequently cited example is the use of highly specialized medical institutions during night-time hours by patients with relatively minor conditions, despite such facilities being primarily intended for individuals requiring hospitalization or surgical intervention.

¹¹⁷ Ministry of Health, Labour and Welfare. *Japan's Medical Insurance System*. <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000172084.pdf>

¹¹⁸ Ministry of Health, Labour and Welfare. *Patient Behavior Survey, Reiwa 5 (2023)*.

In response to these issues, policy measures have been introduced to guide patient healthcare-seeking behavior. In particular, systems have been implemented whereby patients who seek care at highly specialized medical institutions during night-time hours or without a referral incur additional out-of-pocket charges compared with standard visits. These measures aim to encourage more appropriate use of medical resources and to alleviate pressures on advanced care facilities.

4.2 Healthcare Delivery System | Medical Facilities and Hospital Beds

Classification of Medical Facilities

Medical facilities in Japan can be broadly classified into general clinics (with or without inpatient beds), dental clinics, and hospitals. Hospitals and clinics are distinguished on the basis of the number of beds: medical institutions with 20 or more beds are categorized as hospitals, while those with 19 beds or fewer, or without inpatient facilities, are classified as clinics. As of 2024, Japan has 8,060 hospitals, 5,415 clinics with inpatient beds, 99,792 clinics without inpatient beds, and 66,378 dental clinics. An examination of recent trends indicates that the number of hospitals and clinics with inpatient beds has been gradually declining, whereas clinics without inpatient beds have shown an increasing trend.¹¹⁹

With regard to hospitals, there also exists a functional classification system. Specifically, hospitals are categorized into three types: Community Healthcare Support Hospitals, Advanced Treatment Hospitals, and Core Clinical Research Hospitals. These institutions are respectively expected to fulfil key roles in ensuring regional healthcare provision, delivering advanced medical care as well as developing medical technologies and providing medical training, and serving as central hubs for the conduct of clinical research. In contrast to general hospitals that do not fall under these categories, these three types of hospitals are subject to distinct requirements, including specific staffing standards and organizational criteria.¹²⁰

Classification of Hospital Beds

Hospital beds in Japan are categorized into general beds, long-term care beds, psychiatric beds, infectious disease beds, and tuberculosis beds.¹²¹ Staffing standards differ according to each bed category, reflecting the varying levels of care and medical needs associated with each type.

With regard to bed classification, the Fourth Amendment to the Medical Care Act in 2000 introduced a significant reform by subdividing the former category of “other beds” into *long-term care beds* and

¹¹⁹ Ministry of Health, Labour and Welfare. *Survey of Medical Institutions*.

<https://www.mhlw.go.jp/toukei/saikin/hw/iryosd/24/dl/02sisetu06.pdf>

¹²⁰ Ministry of Health, Labour and Welfare. *Annual Health, Labour and Welfare Report 2017 (Heisei 29 Edition)*.

<http://www.mhlw.go.jp/wp/hakusyo/kousei/17-2/dl/02.pdf>

¹²¹ Ministry of Health, Labour and Welfare. *Annual Health, Labour and Welfare Report 2017 (Heisei 29 Edition)*.

<http://www.mhlw.go.jp/wp/hakusyo/kousei/17-2/dl/02.pdf>

general beds, with the aim of ensuring that medical care is more appropriately aligned with patients’ clinical conditions. As illustrated in Figure 4-2-1, general beds constitute the largest proportion among all bed categories.

Figure 4-2-1 Number of Hospital Beds by Type (2024)



Note 1: The figure for psychiatric beds includes beds in both psychiatric hospitals and general hospitals.

Source: Overview of the 2024 Survey of Medical Facilities

The trends observed in general hospital beds can be understood against the backdrop of policies implemented following the achievement of universal health insurance coverage. Measures to reduce patients’ financial burden, such as the introduction of the High-Cost Medical Expense Benefit system, led to an expansion in public demand for medical care, which in turn was accompanied by an increase in the number of hospitals and hospital beds.¹²² Within this context, a significant number of patients occupying general beds are those unable to be discharged despite no longer requiring acute medical care, often due to difficulties in managing daily life after returning home. This phenomenon, commonly referred to as “social hospitalization,” has contributed to the sustained utilization of general hospital beds.

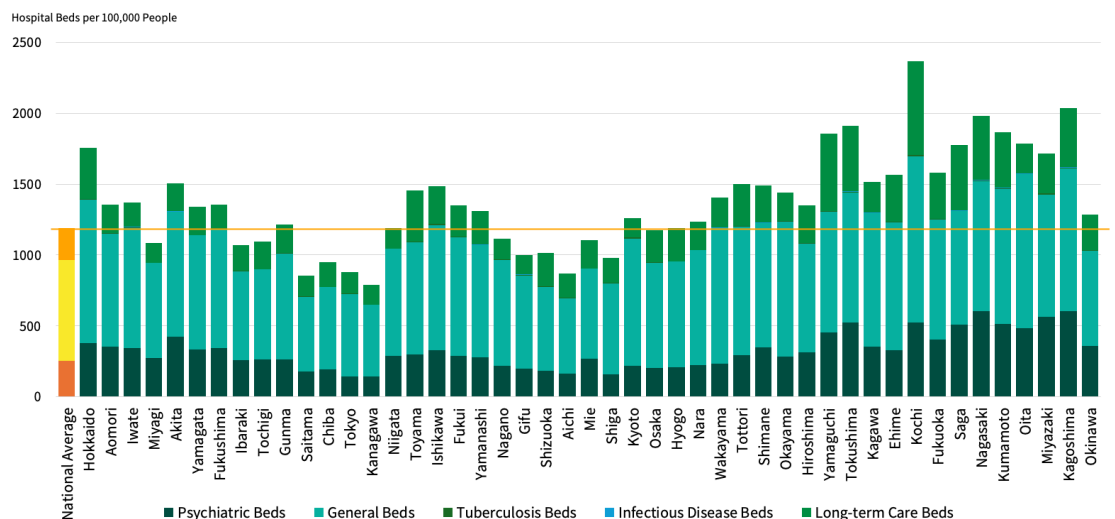
It has been widely noted that all members of the baby boom generation (born between 1947 and 1949) will reach the stage of advanced old age by around 2025, leading to a sharp increase in social security expenditures, including healthcare and long-term care costs. As population ageing continues to accelerate, there is a growing need to utilize limited healthcare resources more efficiently. In response, the government has set a target of reducing the total number of hospital beds to between 1.15 and 1.19 million by 2025. This policy aims to promote the functional differentiation of hospital beds according to the nature of medical needs, ensuring that patients can receive appropriate care, in appropriate settings, and at appropriate times across all regions.

An examination of hospital bed numbers by prefecture reveals substantial regional disparities, as illustrated in Figure 4-2-2. The difference in the number of hospital beds per 100,000 population

¹²² National Federation of Health Insurance Societies (2017). *Medical Security in Figures: 2017 Edition*, Gyōsei Publishing, p. 43.

between Kochi Prefecture, which has the highest number, and Kanagawa Prefecture, which has the lowest, is approximately threefold. It is expected that such regional disparities will be addressed through the development and implementation of Regional Healthcare Plans (see Section 4.4). Under this framework, prefectures report the medical functions of hospital beds to the prefectural governor, and based on these reports, aim to realize an optimal future healthcare delivery system by determining the required volume of each medical function in line with regional needs.

Figure 4-2-2 Number of Hospital Beds per 100,000 People by Prefecture (2024)

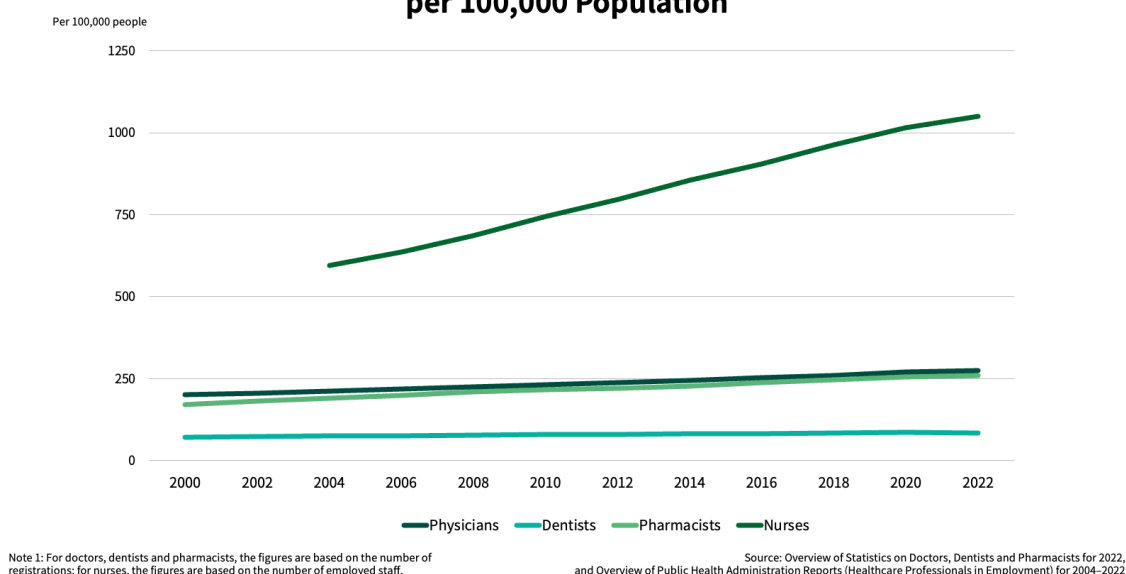


4.3 Healthcare Delivery System | Healthcare Professionals

In Japan, a wide range of occupations related to the provision of medical care are regulated through statutory qualification systems. For many healthcare professions, the law establishes either *exclusive scope of practice*, whereby only individuals holding the relevant national qualification are permitted to perform specified professional duties, or *exclusive use of professional titles*, whereby individuals are prohibited from using a designated professional title, or similar titles, unless they hold the appropriate qualification.

This section focuses in particular on four core healthcare professions: physicians, dentists, pharmacists, and nurses, and examines their roles and regulatory frameworks in greater detail.

Figure 4-3-1 Trends in the Number of Healthcare Professionals per 100,000 Population



Physicians

The total number of registered physicians nationwide has continued to increase steadily, reaching 343,275 as of 2022. At the same time, substantial disparities can be observed among prefectures: physician density tends to be higher in western Japan, while regions in and north of the Kanto area generally have fewer physicians. In addition, it has been noted that the average age of physicians has been rising in recent years. In particular, the average age of physicians working in clinics reached 60.4 years in 2022. Excluding clinical trainees, the distribution of physicians by primary specialty (with one specialty assigned per physician) shows that internal medicine is the most common, followed by orthopedics and pediatrics.¹²³

In recent years, the uneven geographical distribution of physicians and imbalances across medical specialties have emerged as major policy challenges, prompting a range of countermeasures. At the prefectural level, initiatives have included increasing medical school enrolment quotas through regional admission programs and strengthening support through Regional Healthcare Support Centers. In addition, ceiling limits have been introduced in prefectures and specialties where the number of physicians exceeds estimated demand.

Concerns have also been raised regarding the specialist certification system, as it had previously been administered independently by individual academic societies, leading to issues related to consistency in certification standards and the assurance of specialist quality. In response, a new specialist training system was established with the aim of improving the quality of specialists and ensuring the provision of high-quality medical care. This reform introduced a new framework centered on a neutral third-party organization responsible for the unified certification of specialists and the evaluation and

¹²³ Ministry of Health, Labour and Welfare. *Overview of the 2022 (Reiwa 4) Survey of Physicians, Dentists and Pharmacists*. https://www.mhlw.go.jp/toukei/saikin/hw/ishi/22/dl/R04_kekka-1.pdf

accreditation of training programs. The system was fully implemented nationwide in 2018.¹²⁴

From 2024, the “Physicians’ Work Style Reform” was launched. This policy aims to address longstanding practices of excessive working hours among physicians and to ensure the sustainable provision of high-quality and safe medical care for patients. Under this reform, upper limits on overtime work have been introduced, stipulating in principle that physicians’ annual overtime hours should not exceed 960 hours, while allowing for special exemption categories under specific conditions.¹²⁵

Dentists

The total number of registered dentists nationwide has remained relatively stable in recent years, reaching 105,267 as of 2022. A notable characteristic of the dental workforce is that an overwhelming majority of dentists, over 85 per cent, are employed in dental clinics rather than in hospital settings. There are also substantial inter-prefectural disparities in the distribution of dentists. For example, when measured per 100,000 population, Tokyo, which has the highest density, has approximately twice as many dentists as Aomori Prefecture, which has the lowest. In addition, the average age of dentists has been rising steadily, indicating a progressing ageing of the dental workforce.¹²⁶

Pharmacists

The number of registered pharmacists nationwide has continued to increase steadily, reaching 323,690 as of 2022. Pharmacists employed in community pharmacies account for the largest share, at approximately 60 per cent of the total workforce. In terms of age distribution, pharmacists aged 30–39 constitute the largest cohort. Regional disparities are also evident: prefectures such as Tokushima, Hyogo, and Tokyo have relatively high numbers of pharmacists, whereas Okinawa, Fukui, and Aomori have comparatively fewer.¹²⁷

Pharmacists are employed across a wide range of settings, including hospitals and community pharmacies where they are engaged in dispensing, as well as in pharmaceutical companies and pharmaceutical distribution. Looking ahead, however, pharmacists are expected to assume new and expanded roles. A government policy summary released in July 2022 emphasized that, amid rapidly growing healthcare needs and increasing difficulties in securing sufficient healthcare personnel, community pharmacists are expected to play a vital role in supporting the Community-based Integrated Care System. Specifically, the policy highlighted the importance of strengthening patient-facing services, improving the efficiency of dispensing and other product-focused tasks, responding to digitalization and the use of information and communication technologies (ICT), and ensuring that

¹²⁴ Ministry of Health, Labour and Welfare. 2. Measures to Address the Maldistribution of Physicians. http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000184302.pdf

¹²⁵ Ministry of Health, Labour and Welfare. Work Style Reform for Physicians. <https://www.mhlw.go.jp/content/10800000/001129457.pdf>

¹²⁶ Ministry of Health, Labour and Welfare. Overview of the 2022 (Reiwa 4) Survey of Physicians, Dentists and Pharmacists. https://www.mhlw.go.jp/toukei/saikin/hw/ishi/22/dl/R04_kekka-1.pdf

¹²⁷ Ministry of Health, Labour and Welfare. Overview of the 2022 (Reiwa 4) Survey of Physicians, Dentists and Pharmacists. https://www.mhlw.go.jp/toukei/saikin/hw/ishi/22/dl/R04_kekka-1.pdf

pharmacies collectively provide services tailored to the needs of their local communities.

Nursing Personnel and Related Professions

Nursing personnel include not only nurses, but also public health nurses, midwives, and assistant nurses, each of whom follows a distinct training pathway. The total number of nursing personnel has shown a consistent upward trend over time. While hospitals and clinics remain the primary workplaces, recent years have seen particularly high growth in employment within home-visit nursing stations and long-term care insurance facilities.¹²⁸

Approximately 90 per cent of nursing personnel are women, and many experience career interruptions due to childbirth, childrearing, or caregiving responsibilities. As a result, measures to support re-employment, promote workforce retention, and prevent attrition have been actively implemented. Moreover, as population ageing accelerates and the working-age population declines sharply, demand for nursing care is expected to increase further. Consequently, challenges include not only addressing potential shortages in the overall number of nursing personnel, but also correcting geographical imbalances and facilitating shifts from hospital-based employment to home-visit nursing and long-term care settings.

Among nursing personnel, nurses constitute the largest group, numbering 1,311,687 as of 2022. In terms of employment settings, hospitals account for the largest share, followed by clinics and long-term care insurance facilities. The Japanese Nursing Association has established three professional certification systems, Certified Nurse Specialist, Certified Nurse, and Certified Nurse Administrator, to promote the development of highly specialized and advanced nursing professionals.

In addition, since 2015, a training system for nurses authorized to perform specified medical acts has been in place. This program aims to train nurses who can carry out certain medical support activities based on standardized protocols without waiting for direct instructions from physicians or dentists. This initiative is expected to contribute to task shifting and task sharing in the context of physicians' work style reform, as well as to support the expansion of home-based medical care.

In recent years, Japan has also expanded the acceptance of foreign nurses under frameworks such as Economic Partnership Agreements (EPAs) and the Technical Intern Training Program. Nurse candidates are currently accepted from three countries, Indonesia, the Philippines, and Viet Nam, reflecting efforts to address workforce needs while promoting international cooperation in healthcare.

¹²⁸ Ministry of Health, Labour and Welfare. *The Current Situation Surrounding the Securing of Nurses and Other Nursing Personnel*. <https://www.mhlw.go.jp/content/10800000/001118192.pdf>

**Table 4-3-1 Number of Licensed Professionals
in other Healthcare-related Occupations**
(as at the end of the 2023 financial year)

Radiographer	Clinical Laboratory Technologist	Physiotherapist	Occupational Therapist	Orthoptist	Speech and Language Therapist	Clinical Engineer
98,872	217,369	213,610	113,830	19,350	39,860	54,365

Prosthetist and Orthotist	Dental Hygienist	Dental Technician	Emergency (Life-Saving) Technician	Anma Massage and Shiatsu Practitioner	Acupuncturist	Moxibustion Practitioner	Judo Therapist
6,125	314,143	123,870	72,849	210,294	192,521	191,292	93,105

Note 1: For dental hygienists and dental technicians, figures as of the end of fiscal year 2022 are used.

Source: Health, Labour and Welfare Statistics Association, Trends in National Health, Vol. 71, No. 9.

Gender Distribution among Healthcare Professionals

The gender balance among healthcare professionals in Japan remains markedly uneven. As of 2022, 76.4 per cent of physicians were male. Although the proportion of female physicians has been increasing in recent years, women continue to be underrepresented overall. A generational shift is nevertheless evident: while women account for only 20.9 per cent of physicians in the 50–59 age group, their share rises to 36.2 per cent among those aged 29 and under.

In contrast, women constitute the majority of pharmacists and nurses. Specifically, women accounted for 61.6 per cent of pharmacists and as many as 91.4 per cent of nurses in 2022, highlighting a pronounced gendered division of labor across healthcare professions in Japan.

4.4 Healthcare Delivery System | Planning of Regional Healthcare

Provision

As Japan's healthcare delivery system is predominantly centered on the private sector, various initiatives have been implemented, led primarily by prefectural governments, to ensure coordination among medical institutions and to establish an efficient and high-quality healthcare delivery system. To this end, geographical units known as *medical service areas* have been designated, within which regional healthcare planning and coordination are undertaken. Among these, the *secondary medical service area* constitutes a particularly important unit.

A secondary medical service area is defined by prefectural governments as a geographical unit within which it is considered appropriate to provide inpatient medical care through hospitals and clinics as an

integrated system. As of April 2024, there are 330 such medical service areas nationwide. In recent years, significant regional disparities in population structure and the distribution of healthcare resources have become increasingly evident. As a result, initiatives undertaken at the prefectural and medical service area levels play a crucial role in designing healthcare delivery systems that are responsive to local conditions, as well as in strengthening coordination between healthcare and long-term care services.

At the national level, the government supports these efforts by presenting uniform indicators applicable across the country and by setting out detailed requirements for the formulation of medical care plans, thereby providing a common analytical and planning framework for prefectures. Specific initiatives undertaken within this framework are outlined below.

Medical Care Plans

Medical care plans were established through the 1985 amendment to the Medical Care Act with the aim of promoting the development of regional healthcare delivery systems and ensuring the efficient utilization of medical resources. As population structures and the availability of healthcare resources vary significantly across regions, each prefecture formulates its own medical care plan in line with local circumstances. The objective of these plans is to promote the appropriate functional differentiation and coordination of medical services within each region, and to establish a seamless system through which necessary healthcare can be provided continuously across the community.

The contents of medical care plans include targets to be achieved with respect to *five priority diseases*; cancer, stroke, cardiovascular diseases, diabetes, and mental disorders, and *six priority healthcare services*, including emergency medical care and medical services provided during disasters (including periods of infectious disease outbreaks such as emerging infections), as well as home-based medical care. In addition, the plans specify healthcare coordination frameworks, measures to secure healthcare personnel, strategies for providing information to residents, initiatives to ensure patient safety, the designation of secondary and tertiary medical service areas, and the calculation of standard numbers of hospital beds. These contents are reviewed periodically in accordance with amendments to the Medical Care Act and related policy reform

Regional Healthcare Vision¹²⁹

In anticipation of 2025, when the baby boom generation will reach the age of 75 and above and healthcare and long-term care expenditures are expected to rise sharply, the formulation of a *Regional Healthcare Vision* was mandated from 2018 as a component of prefectural medical care plans. The purpose of this initiative is to establish high-quality and efficient healthcare delivery systems tailored to regional needs. Under this framework, prefectures are required to estimate future healthcare demand and the required number of hospital beds by 2025 for each planning area and for each of four

¹²⁹ Health, Labour and Welfare Statistics Association (General Incorporated Foundation). *Trends in National Health*, Vol. 71, No. 9, 2024/2025.

functional categories: highly acute care, acute care, recovery care, and chronic care. Based on these estimates, prefectures are expected to develop concrete policy measures.

The planning areas used for Regional Healthcare Visions are, in principle, based on existing secondary medical service areas, but are defined with consideration given to changes in population structure, trends in healthcare demand, and the distribution of healthcare professionals and medical institutions. The Regional Healthcare Vision specifies projected healthcare demand in 2025 (including inpatient and outpatient demand and disease-specific patient numbers), the desired future configuration of healthcare delivery systems (including the required volume of medical functions by secondary medical service area), and the measures necessary to realize this vision.

Following formulation, prefectures are required to convene Regional Healthcare Vision Coordination Meetings on an ongoing basis within each planning area. These meetings bring together healthcare providers, health insurers, and other relevant stakeholders to discuss: (1) concrete response policies for individual medical institutions; (2) measures for medical institutions with wards in which all beds are not fully utilized; and (3) responses to the establishment of new medical institutions or increases in bed numbers.

Beyond 2025, a new Regional Healthcare Vision will be developed with a view towards around 2040, when the population aged 85 and over is expected to increase substantially while the working-age population declines. In addition to existing considerations, major challenges will include strengthening coordination between healthcare and long-term care services and reassessing the overall structure of regional healthcare delivery systems, including the roles of primary care physicians and home-based medical care.

Physician Supply Plan

The 2018 amendment to the Medical Care Act also introduced the requirement to formulate *Physician Supply Plans* in order to secure healthcare provision at the regional level by addressing geographical disparities in physician distribution. Under this framework, prefectures use physician maldistribution indicators to classify secondary medical service areas into physician-shortage areas and physician-surplus areas, and implement physician supply measures accordingly.

In physician-shortage areas, defined as those falling within the lowest 33.3 per cent according to the maldistribution indicator, prefectures set target numbers of physicians and implement measures to achieve these targets. These measures include coordinating physician placements, developing career formation programs, and establishing regional admission quotas and local origin quotas in medical schools.¹³⁰ Conversely, areas classified as physician-surplus areas, those in the highest 33.3 per cent are, in principle, not permitted to recruit physicians from other medical service areas, and may instead dispatch physicians to shortage areas as necessary.¹³¹

¹³⁰ Health, Labour and Welfare Statistics Association (General Incorporated Foundation). *Trends in National Health*, Vol. 71, No. 9, 2024/2025.

¹³¹ Ministry of Health, Labour and Welfare. *Guidelines for the Formulation of Physician Recruitment Plans: The Eighth Medical Care Plan (First Phase)*. <https://www.mhlw.go.jp/content/001083986.pdf>

Outpatient Care Plan

With respect to outpatient care, the 2018 amendment to the Medical Care Act mandated the formulation of *Outpatient Care Plans* by each prefecture in order to address issues such as increasing sub-specialization and the concentration of clinics without inpatient beds in urban areas. Prefectures use outpatient physician maldistribution indicators to designate outpatient physician-surplus areas and incorporate into their plans measures such as information provision to new clinic entrants, the establishment of consultation forums on outpatient care, plans for the efficient use of medical equipment, and assessments of regional outpatient care provision.¹³²

Furthermore, the *Outpatient Function Reporting System* was introduced in 2022. Based on the outcomes of this reporting process and subsequent consultations, medical institutions that reach agreement with relevant stakeholders are publicly designated as *Referral-based Priority Medical Institutions*. These institutions specialize in providing outpatient care to patients referred with formal referral letters. Patients who attend such institutions without a referral are required to pay an additional charge (designated medical expense) on top of the standard 30 per cent patient co-payment. This policy is expected to contribute to shorter waiting times for outpatient consultations and to reduce the workload of hospital-based physicians.¹³³

¹³² Health, Labour and Welfare Statistics Association (General Incorporated Foundation). *Trends in National Health*, Vol. 71, No. 9, 2024/2025.

¹³³ Ministry of Health, Labour and Welfare. *On Referral-Based Core Medical Institutions*.
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000123022_00003.html

Japanese Health Policy

5. Pharmaceuticals and Medical Devices

September 2026

5.1 Pharmaceuticals and Medical Devices | Overview

Overview of the Regulatory Framework for Pharmaceuticals and Medical Devices

The principal legislation forming the foundation of the pharmaceutical and medical device regulatory system is the *Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* (commonly referred to as the Pharmaceuticals and Medical Devices Act, or PMD Act). As pharmaceuticals and medical devices exert direct effects on the human body, they carry significant potential to cause harm to life or health. For this reason, regulation under the PMD Act is deemed necessary.

The degree of regulatory control varies according to the classification of the pharmaceutical or medical device concerned.

Principal Regulatory Categories and Representative Examples

Regulatory Category	Main Classifications and Representative Examples
Pharmaceuticals	Prescription medicines
	Over-the-counter medicines (Pharmacist-supervised medicines; General OTC medicines [Class 1–Class 3])
	In vitro diagnostic pharmaceuticals (e.g., hematological diagnostic reagents)
Quasi-pharmaceuticals	Gargle solutions, insecticides, hair dyes, nutritional tonic drinks
Cosmetics	General cosmetic products, shampoos, skincare products
Medical Devices	Pacemakers, artificial joints, ultrasound diagnostic imaging systems, surgical scalpels
Regenerative Medicine Products	Processed cell-based products (e.g., myocardial cell sheets)
	Gene therapy products (e.g., products involving administration of functional genes to compensate for genetic deficiencies)

Pharmaceuticals and medical devices are subject to regulatory oversight at each stage, from research and development through to post-marketing impact. The specific nature of such regulation varies depending on the classification of the product concerned.

Regulatory Framework under the Pharmaceuticals and Medical Devices Act

1	Development and Clinical Trials	Regulation of clinical trial methodologies and data collection processes to ensure the quality, efficacy, and safety of pharmaceuticals and related products.
2	Marketing Authorisation Review	The Pharmaceuticals and Medical Devices Agency (PMDA) conducts a scientific review of quality, efficacy, and safety. Following deliberation by the Pharmaceutical Affairs and Food Sanitation Council, marketing authorization is granted by the Minister of Health, Labour and Welfare.
3	Manufacturing	Regulation of manufacturing and marketing authorization holders from the standpoint of quality assurance.
4	Distribution and Sales Regulation	Regulation of distribution channels for pharmaceuticals and related products (including pharmacies and retail outlets). Regulation of labelling, including outer packaging and package inserts.
5	Post-Marketing Safety Measures	Collection of information regarding adverse reactions. Implementation of safety measures to prevent the expansion of adverse effects (including revision of package inserts where necessary).
6	Regulatory Supervision and Enforcement	Monitoring and enforcement against unapproved or unlicensed pharmaceuticals. Control and removal of defective or non-compliant products.
7	Relief for Adverse Drug Reactions	Provision of compensation under the Adverse Drug Reaction Relief System and related schemes. (As stipulated under the Act on the Pharmaceuticals and Medical Devices Agency.)

The fundamental structure of the current pharmaceutical and medical device regulatory system was established through the comprehensive revision of the former Pharmaceutical Affairs Act in 1960, which set out regulations to ensure quality, efficacy, and safety.

Subsequently, a major amendment was enacted in 2013, at which time the legislation was renamed the *Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices*. This reform introduced regulatory provisions reflecting the specific characteristics of medical devices and established a formal approval framework for regenerative medicine products.¹³⁴

In recent years, additional provisions have been incorporated, including regulations governing the

¹³⁴ Ministry of Health, Labour and Welfare. (2013). *Overview of the Act for Partial Revision of the Pharmaceutical Affairs Act (Act No. 84 of 2013)*. <https://www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/0000066816.pdf>

marketing of regenerative medicine products, emergency approval mechanisms for pharmaceuticals, and the introduction of electronic prescription systems based on an online eligibility verification infrastructure.¹³⁵

Distribution and Pricing of Pharmaceuticals and Medical Devices

Within the broader framework of pharmaceutical and medical device regulation outlined above, this section focuses primarily on distribution (manufacturing and sales) and price determination. Regulatory requirements governing the domestic distribution of pharmaceuticals and medical devices may be categorized into two types: those relating to the product itself and those relating to business operators. Only upon satisfying both categories of regulation may pharmaceuticals and medical devices lawfully be placed on the market.

Once products enter the market, their prices are determined either by officially set prices or by the free market. Official prices refer to those applied to pharmaceuticals and medical devices provided under the public health insurance system, with the government determining the reimbursement level. As noted in Section 1.2, the majority of medical care in Japan is delivered within the framework of insured medical services; consequently, prescription pharmaceuticals and medical devices are strongly influenced by government price setting. By contrast, over-the-counter medicines and home-use medical devices that are not covered by public insurance are priced according to market mechanisms. In practice, insured medical care operates through a combination of free-market pricing and official reimbursement pricing. This dual structure, particularly in relation to pharmaceuticals, has frequently constituted a central issue in health policy reform debates.

Specifically, while medical services provided by hospitals, clinics, and pharmacies to patients are reimbursed at officially determined prices, medical institutions purchase pharmaceuticals from wholesalers at prices determined through market negotiations. Similarly, transactions between wholesalers and pharmaceutical manufacturers are conducted within the free market. In general, prices negotiated in the free market tend to be lower than the official reimbursement prices. Consequently, medical institutions may derive a margin from the difference between the procurement price and the official reimbursement price, commonly referred to as the “drug price margin.”

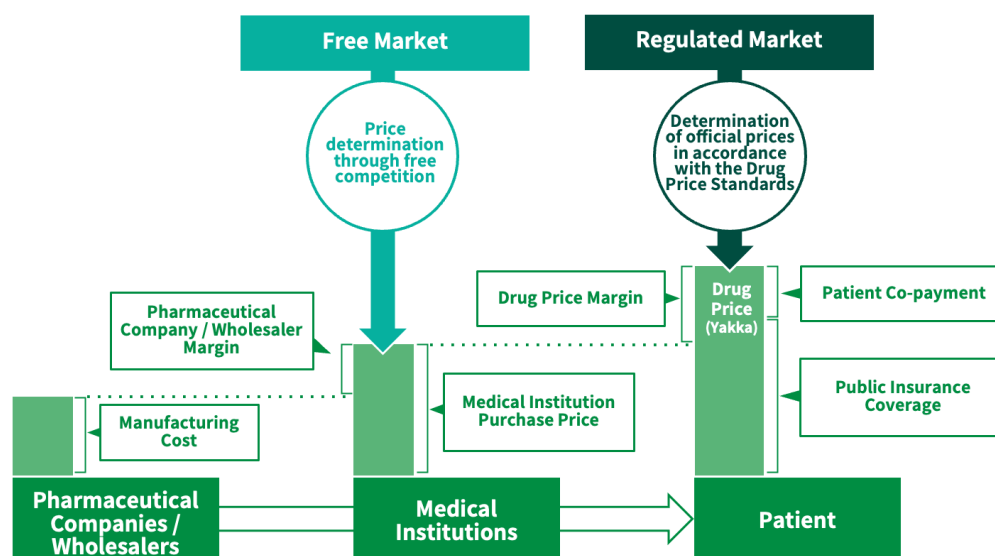
In light of this, the government has, where such margins are deemed excessive, considered that there is scope to reduce official reimbursement prices and has accordingly implemented price reductions during periodic drug price revisions.

However, in recent years, rising costs of raw materials, labor, and distribution have led in certain cases to situations in which procurement prices exceed official reimbursement prices, a phenomenon often described as a “negative margin.” This development has placed increasing financial pressure on medical institutions.

¹³⁵ Yonemura, S. (n.d.). *Lectures on medical law* (2nd ed.).

Health, Labour and Welfare Statistics Association. (2024). *Health and welfare statistics in Japan 2024/2025 (Trends in national health)*.

Figure 5-1-1 Distribution and Pricing of Pharmaceuticals and Medical Devices



From Regulatory Approval to Health Insurance Coverage

An overview of the process from regulatory approval to inclusion under the public health insurance system is set out below.

“Regulatory approval” refers to the process under the *Pharmaceuticals and Medical Devices Act* (PMD Act) by which a pharmaceutical or medical device receives authorization from the regulatory authorities to ensure its quality, efficacy, and safety.

“Health insurance coverage,” by contrast, refers to the subsequent process under the medical insurance system whereby an official reimbursement price is determined, and the product is included within the scope of insured medical treatment.

Further details of each stage are provided in Sections 5.2 onwards, organized by product classification.

1) Regulatory Approval

In Japan, any entity seeking to manufacture and market pharmaceuticals or medical devices must apply for approval to the Minister of Health, Labour and Welfare (MHLW).

Although formal approval is granted by the Minister, the scientific review of quality, efficacy, and safety is conducted by the Pharmaceuticals and Medical Devices Agency (PMDA), an independent administrative agency.

Once approval is granted, the pharmaceutical or medical device may legally be used.

2) Inclusion under the Public Health Insurance System

Regulatory approval alone does not confer coverage under public health insurance. As discussed in Section 1.2, insured medical care constitutes most of the healthcare provision in Japan. Accordingly, for pharmaceuticals and medical devices to be widely adopted in clinical practice, it is generally crucial

that an official reimbursement price be determined and that the product be included within the scope of insurance coverage.

a) Pharmaceuticals

Following regulatory approval, a company seeking reimbursement must submit an application for insurance listing to the MHLW.

The Central Social Insurance Medical Council (Chuikyo), an advisory body to the Minister, then assesses and determines the official reimbursement price (the “drug price”).¹³⁶

The determined price is added to the *Drug Price Standard*, the official list of reimbursable pharmaceutical prices, thereby rendering the product eligible for insurance coverage.

Drug prices are calculated with reference to:

- The prices of existing drugs with similar indications or therapeutic effects; and
- Cost data submitted by the manufacturer.

In principle, listing occurs within 60 days of regulatory approval, and no later than 90 days.

Prescription pharmaceuticals are, as a general rule, included under insurance coverage.¹³⁷

b) Medical Devices

For medical devices, procedures for insurance coverage differ depending on the reimbursement evaluation category assigned to the device.

An outline of these categories is provided in Section 5.5. Given the complexity of the evaluation framework, the Ministry of Health, Labour and Welfare recommends confirming the appropriate evaluation category through consultation with the PMDA’s centralized consultation service for Software as a Medical Device (SaMD)¹³⁸ and related medical device programs.¹³⁹

Market Size of Pharmaceuticals and Medical Devices¹⁴⁰

Japan accounts for approximately 4.2¹⁴¹ per cent of the global pharmaceutical market and approximately 5.0¹⁴² per cent of the global medical device market.

The domestic market for prescription pharmaceuticals in Japan has continued to expand. As of 2023:

- Domestic production amounted to approximately ¥10 trillion.¹⁴³

¹³⁶ Ministry of Health, Labour and Welfare. (2024). *Drug price standard listing and information on generic drugs (valid until March 31, 2025)*. <https://www.mhlw.go.jp/topics/2024/04/tp20240401-01.html>

¹³⁷ On the other hand, certain pharmaceuticals that are not intended to treat life-threatening conditions but are used primarily to improve quality of life are referred to as “lifestyle improvement drugs” and are generally not covered by public health insurance.

¹³⁸ Pharmaceuticals and Medical Devices Agency. (n.d.). *SaMD one-stop consultation service (comprehensive consultation for medical device software)*. <https://www.pmda.go.jp/review-services/f2f-pre/strategies/0011.html>

¹³⁹ Ministry of Health, Labour and Welfare. (2024). *Guidebook on health insurance coverage for medical devices and in vitro diagnostics in FY2024*. <https://www.mhlw.go.jp/content/10800000/001073851.pdf>

¹⁴⁰ Ministry of Health, Labour and Welfare. (2023). *Annual pharmaceutical industry production statistics survey (2023)*. <https://www.e-stat.go.jp/stat-search/files?tclass=000001224240&cycle=7&year=20230> Health, Labour and Welfare Statistics Association. (2024). *Health and welfare statistics in Japan 2024/2025 (Trends in national health)*.

¹⁴¹ IQVIA Institute for Human Data Science. (n.d.). *Global use of medicines: Outlook through 2029*.

¹⁴² Ministry of Economy, Trade and Industry Medical Device Industry Vision Study Group. (2024). *Medical device industry vision 2024*.

¹⁴³ Although the figures for 2023 appear to show a significant increase, this is largely attributable to changes in the statistical survey methodology, including a substantial improvement in the response rate.

- Imports totalled approximately ¥3.8 trillion.
- Combined, the total market size was just under ¥14 trillion.

The production scale of pharmacist-supervised and general over-the-counter medicines has also been increasing, reaching approximately ¥880 billion. This represents roughly 10 per cent of total domestic pharmaceutical production.

The domestic medical device market has likewise continued to grow. As of 2023:

- Domestic production amounted to approximately ¥2.7 trillion (a year-on-year increase of 3.6 per cent).
- Imports totaled approximately ¥3.3 trillion (a year-on-year increase of 13.8 per cent).
- Combined, the total market size was just under ¥6 trillion.

Compared with pharmaceuticals, the medical device market in Japan exhibits a more import-dependent structural profile.

Table 5-1-1 Trends in the Value of Pharmaceutical Production

	Production			Prescription Medication			Medicines requiring guidance / Over-the-counter medicines					
	Amount (Million Yen)	Growth Rate (%)	Component Ratio (%)	Amount (Million Yen)	Growth Rate (%)	Component Ratio (%)	Amount (Million Yen)	Growth Rate (%)	Component Ratio (%)	First-aid kit for home use		
										Amount (Million Yen)	Growth Rate (%)	Component Ratio (%)
2014	6,589,762	-4.4	100	5,868,927	-5.2	89.1	720,835	3	10.9	20,459	-9.6	0.3
2015	6,748,121	2.4	100	5,996,890	2.2	88.9	751,231	4.2	11.1	18,962	-7.3	0.3
2016	6,623,860	-1.8	100	5,871,373	-2.1	88.6	752,487	0.2	11.4	17,276	-8.9	0.3
2017	6,721,317	1.5	100	6,007,419	2.3	89.4	713,898	-5.1	10.6	14,272	-17.4	0.2
2018	6,907,722	2.8	100	6,172,570	2.7	89.4	735,152	3	10.6	14,224	-0.3	0.2
2019	9,281,471	34.4	100	8,458,427	37	91.1	823,044	12	8.9	2,725	-80.8	0
2020	9,029,561	-2.7	100	8,243,750	-2.5	91.3	785,811	-4.5	8.7	2,462	-9.6	0
2021	8,938,312	-1	100	8,189,133	-0.7	91.6	749,179	-4.7	8.4	2,548	3.5	0
2022	9,833,166	10	100	9,079,086	10.9	92.3	754,079	0.7	7.7	2,186	-14.2	0
2023	10,033,216	2	100	9,152,877	0.8	91.2	880,339	16.7	8.8	2,349	7.5	0

Source: '2023 Survey on Production Trends in the Pharmaceutical Industry' <https://www.e-stat.go.jp/stat-search/files?tclass=000001224240&cycle=7&year=20230;>
'Trends in Public Health 2024/2025' by the Japan Association of Health and Labour Statistics, and others

Table 5-1-2 Trends in the Value of Medical Device Production

	Production Amount (Million Yen)	Year-on-year Change		Index (%)	Average monthly production value (million yen)
		Change (Million Yen)	Percentage (%)		
2014	1,989,497	84,005	4.4	100.0	165,791
2015	1,945,599	-43,898	-2.2	97.8	162,133
2016	1,914,551	-31,048	-1.6	96.2	159,546
2017	1,990,373	75,822	4	100.0	165,864
2018	1,948,961	-41,412	-2.1	98.0	162,413
2019	2,494,164	545,203	28	125.4	207,847
2020	2,403,590	-90,573	-3.6	120.8	200,299
2021	2,604,294	200,704	8.4	130.9	217,024
2022	2,582,869	-21,425	-0.8	130	215,239
2023	2,674,789	91,920	3.6	134	222,899

Note: The index is based on 2014=100

Source: '2023 Survey on Production Trends in the Pharmaceutical Industry' <https://www.e-stat.go.jp/stat-search/files?tclass=00001224240&cycle=7&year=20230>, and 'Trends in Public Health 2024/2025' by the Japan Association of Health and Labour Statistics, and others

Pharmaceuticals are broadly categorized into prescription pharmaceuticals and non-prescription (over-the-counter) pharmaceuticals.

Prescription pharmaceuticals are further divided into originator pharmaceuticals and generic pharmaceuticals. The definitions of each are set out below.

Prescription Pharmaceuticals Pharmaceutical products supplied for use by a physician or dentist, or for use in accordance with a prescription or instruction issued by such professionals.	Originator Pharmaceuticals: Pharmaceuticals possessing new indications or therapeutic effects, whose efficacy and safety have been confirmed through clinical trials and other studies, and which have subsequently received regulatory approval. ¹⁴⁴
	Generic Pharmaceuticals: Pharmaceuticals approved after the expiry of the patent of an originator product, which contain the same active ingredients and specifications as the originator and are recognized as therapeutically equivalent.
Pharmacist-Supervised Medicines Pharmaceuticals that do not require a prescription for sale or purchase, but for which face-to-face	

¹⁴⁴ Ministry of Health, Labour and Welfare. (2025). *Drug price standard listing and information on generic drugs (effective August 14, 2025)*. <https://www.mhlw.go.jp/topics/2025/04/tp20250401-01.html>

information provision and guidance by a pharmacist are legally required. Online sales of such products are prohibited. <i>(Further details are provided in Section 5.4 on non-prescription medicines.)</i>	
Non-Prescription (Over-the-Counter) Pharmaceuticals Pharmaceutical products other than prescription pharmaceuticals.	–

From Section 5.2 onwards, this chapter provides a detailed explanation of each pharmaceutical category and medical devices, following the sequence of regulatory approval and subsequent inclusion under the public health insurance system, together with relevant institutional considerations and practical points of note.

5.2 Pharmaceuticals and Medical Devices | Originator

Pharmaceuticals

Definition of Originator Pharmaceuticals

An originator pharmaceutical (new pharmaceutical product) is defined under Article 14-4 of the *Pharmaceuticals and Medical Devices Act* as a pharmaceutical product that clearly differs from already approved pharmaceuticals in terms of active ingredient, quantity, dosage and administration, indications, or therapeutic effects.

This category primarily includes:

- Pharmaceuticals containing new active ingredients
- New combination prescription products
- Pharmaceuticals with new routes of administration
- Pharmaceuticals with new indications
- Pharmaceuticals with new dosage forms
- Pharmaceuticals with new dosage strengths¹⁴⁵

Approval of Prescription Pharmaceuticals

In order for a pharmaceutical company to manufacture, distribute, and market a new pharmaceutical

¹⁴⁵ Pharmaceuticals and Medical Devices Agency. (n.d.). *New drugs (ethical drugs)*. <https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/p-drugs/0021.html>

product, the following steps are required.

First, marketing authorization must be obtained. The Pharmaceuticals and Medical Devices Agency (PMDA) conducts a scientific review and grants approval based on an evaluation of efficacy and safety data derived from clinical trials.

Clinical trial data and submitted documentation must comply with standards established by the MHLW, including:

- Good Laboratory Practice (GLP), governing non-clinical studies concerning quality and safety; and
- Good Clinical Practice (GCP), governing the conduct of clinical trials.

The PMDA has established a target total review period of 12 months from the date of application acceptance to approval under the standard review process.¹⁴⁶

Following a positive review by the PMDA, the MHLW formally seeks advice from the Pharmaceutical Affairs and Food Sanitation Council. Based on the Council's recommendation, the Minister determines whether to grant final approval.

Expedited and Special Approval Pathways

In addition to the standard approval process, the MHLW has introduced mechanisms to prioritize the review and approval of innovative pharmaceuticals.

1. Sakigake Designation System (Introduced in 2014)

In 2014, Japan introduced the *Sakigake Designation System* to provide patients with the world's most advanced therapies at the earliest possible stage. This system grants priority and accelerated review to pharmaceutical products that are developed in Japan and for which the first marketing authorization application is submitted in Japan.

To qualify, a new pharmaceutical must meet the following four criteria:

1. Innovative therapeutic characteristics
2. Seriousness of the target disease
3. Outstanding efficacy in relation to the target disease
4. Commitment and capacity to pursue early development and application in Japan ahead of the rest of the world¹⁴⁷

2. Conditional Early Approval System (Introduced in 2017)

In 2017, Japan introduced the *Conditional Early Approval System* for pharmaceuticals intended to treat diseases characterized by a small patient population, limited treatment options and difficulty in

¹⁴⁶ Pharmaceuticals and Medical Devices Agency. (n.d.). *Timeline in the standard review process for new drug approvals*.

<https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/p-drugs/0014.html>

¹⁴⁷ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the Sakigake designation system*.

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/tp150514-01_00001.html

conducting confirmatory clinical trials, in which significant unmet medical needs exist. Under this system, pharmaceutical companies may apply for approval based on clinical data demonstrating a certain level of efficacy and safety, even if confirmatory clinical trials have not yet been completed. Approval is granted on the condition that post-marketing studies and investigations are conducted to reconfirm efficacy and safety.

Several pharmaceutical products have already been approved under this framework.¹⁴⁸

Safety and Quality of Prescription Pharmaceuticals

As in other major jurisdictions, the development, manufacture, and marketing of pharmaceuticals in Japan are governed by regulatory standards collectively referred to as GxP (Good Practice standards). These include:

- **GLP (Good Laboratory Practice)** for non-clinical studies;
- **GCP (Good Clinical Practice)** for clinical trials;
- **GMP (Good Manufacturing Practice)** for manufacturing and quality control at production sites; and
- **GVP (Good Vigilance Practice)** for post-marketing safety management.

Together, these standards regulate the entire lifecycle of pharmaceuticals, from development to manufacturing control.

At the same time, Japan's regulatory framework contains several distinctive features concerning product quality and safety.

1. The “Three Responsible Officers” (San'yaku) System

Under the Pharmaceuticals and Medical Devices Act, in order to comply with Good Quality Practice (GQP) and GVP requirements for pharmaceuticals, quasi-pharmaceuticals, cosmetics, and regenerative medicine products, pharmaceutical companies are required to appoint three responsible officers who oversee and control activities related to product quality and safety.¹⁴⁹

These are commonly referred to as the “three key officers”:

- **General Marketing Compliance Officer**
(Seikatsu Seizō Hanbai Sekininsha)
The individual who bears overall responsibility for quality management and post-marketing safety management operations.
- **Quality Assurance Manager**
A person capable of appropriately and effectively conducting quality control operations in accordance with GQP requirements.

¹⁴⁸ Ministry of Health, Labour and Welfare. (n.d.). *Conditional approval system for pharmaceuticals*. <https://www.mhlw.go.jp/content/10601000/000954228.pdf>

¹⁴⁹ Ministry of Health, Labour and Welfare. (n.d.). *Points to note regarding the appropriate implementation of duties by the three key roles in marketing authorization holders (Appendix)*. <https://www.mhlw.go.jp/content/11120000/000804704.pdf>

- **Safety Manager**

A person capable of appropriately and effectively conducting safety assurance operations in accordance with GVP requirements.

2. Early Post-Marketing Surveillance (Immediate Post-Marketing Study)¹⁵⁰

Following approval of a new pharmaceutical, an *early post-marketing surveillance* program is mandatory.

After approval, the MHLW requires the marketing authorization holder to conduct post-marketing surveillance activities to monitor and ensure patient safety. This surveillance is typically conducted for six months following market launch.

The purpose of this surveillance, conducted in accordance with Good Post-marketing Study Practice (GPSP), is to detect serious adverse reactions that may not have been observed during clinical trials but could emerge in real-world clinical use.¹⁵¹

3. Initial Prescription Period Restriction

To further safeguard patient safety, newly listed pharmaceuticals are, in principle, subject to a restriction limiting prescriptions to a maximum of 14 days during the first year following listing in the reimbursement schedule.

However, the Central Social Insurance Medical Council (Chuikyo) may grant exceptions for pharmaceuticals that meet either of the following criteria¹⁵²:

- A new pharmaceutical containing an active ingredient that has substantially the same indications, dosage, and administration as an already listed product with more than one year of clinical use experience (e.g., certain new combination prescription products); or
- A pharmaceutical for which, due to disease characteristics or formulation properties, only dosage forms exceeding 14 days' supply exist, and for which safety beyond a 14-day administration period has been confirmed.

Determination of Drug Prices for Originator Pharmaceuticals¹⁵³

The “drug price” refers to the amount determined for each branded pharmaceutical as the average per-unit cost required by insured medical institutions and pharmacies to supply the drug. This amount corresponds to the reimbursement paid to such institutions for pharmaceuticals used in patient treatment.

After obtaining marketing approval, the manufacturer submits an application for price listing to the

¹⁵⁰ Ministry of Health, Labour and Welfare. (n.d.). *Implementation methods for early post-marketing phase vigilance for prescription drugs*. <https://www.mhlw.go.jp/content/11120000/000945083.pdf>

¹⁵¹ Pharmaceuticals and Medical Devices Agency. (n.d.). *Information on early post-marketing phase vigilance*. <https://www.pmda.go.jp/review-services/drug-reviews/review-information/p-drugs/0006.html>

¹⁵² Ministry of Health, Labour and Welfare. (n.d.). *Handling of prescription duration limits for new drugs* (p. 4). <https://www.mhlw.go.jp/content/12404000/001242877.pdf>

¹⁵³ Ministry of Health, Labour and Welfare, Health Bureau. (2025). *Standards for drug price calculation* (issued February 19, 2025). <https://www.mhlw.go.jp/content/12404000/001416107.pdf>

Minister of Health, Labour and Welfare. Following necessary adjustments, the proposed price is reported to and approved by the plenary session of the Central Social Insurance Medical Council (Chuikyo). The pharmaceutical becomes eligible for insurance coverage upon listing in the Drug Price Standard.

Figure 5-2-1 Basic Principles of Drug Price Calculation

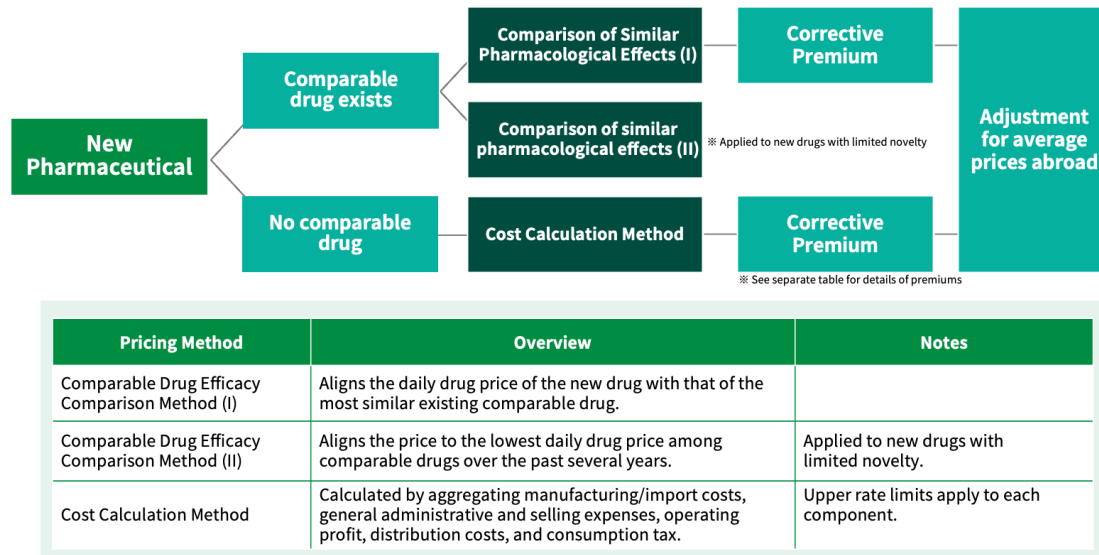
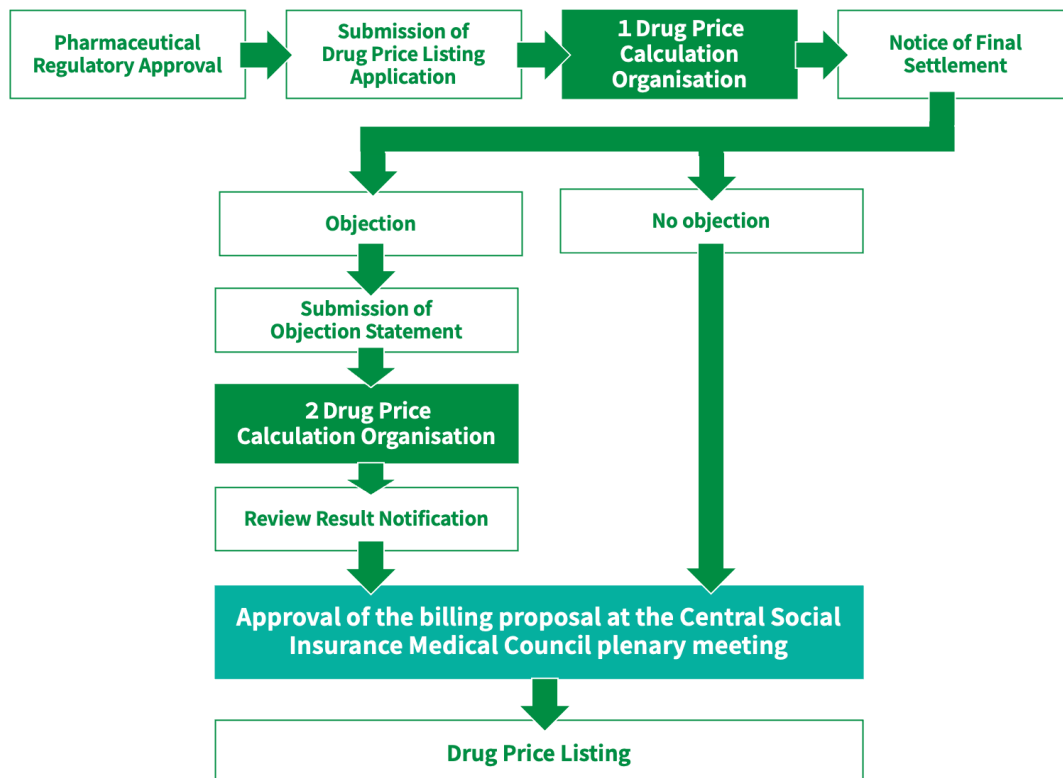


Figure 5-2-2 Key Steps in the Drug Pricing Process



Initial Determination of Drug Prices

At the time of initial listing, drug prices are determined according to one of two principal methods:

- **Similar Efficacy Comparison Method:** Applied when comparable pharmaceuticals with similar therapeutic effects already exist on the market.
- **Cost Calculation Method:** Applied when no comparable approved pharmaceutical exists.¹⁵⁴

In addition, in order to restrain prices of pharmaceuticals assessed as having limited innovativeness while incentivizing the development of highly innovative products, a system of premium price adjustments (corrective add-on premiums) has been introduced.^{155,156} Furthermore, to ensure fair market competition, a **Foreign Average Price Adjustment** mechanism is applied in cases where, under the cost calculation method or in cases lacking comparable pharmacological products, the Japanese price deviates significantly from the average foreign price (defined as 1.25 times or more, or 0.75 times or less, of the average foreign price). In such cases, price adjustments are implemented accordingly.¹⁵⁷

Types of Premium	Overview	Premium Rate
Breakthrough Premium	Applied to pharmaceuticals demonstrating a novel mechanism of action, high efficacy and safety, and a significant improvement in methods of treating disease	70-120%
Usefulness Premium	Applied to pharmaceuticals demonstrating high efficacy and safety and/or improvement in therapeutic methods	5-60%
Marketability Premium	Applied to products such as orphan drugs for rare diseases	5-20%
Pediatric Premium	Applied where pediatric dosage and administration are explicitly included in the approved indications	5-20%
Specific Use Premium	Applied where high usefulness is recognized for a specific therapeutic use	5-20%
Sakigake (Pioneer) Premium	Applied where high usefulness is recognized for a pioneering or first-in-class therapeutic use	10-20%

¹⁵⁴ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the current drug pricing system.*
<https://www.mhlw.go.jp/content/10808000/001276014.pdf>

¹⁵⁵ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the current drug pricing system.*
<https://www.mhlw.go.jp/content/10808000/001276014.pdf>

¹⁵⁶ In this context, irrespective of whether the drug price is calculated using the comparable method or the cost accounting method, it is subject to adjustment premiums.

¹⁵⁷ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the current drug pricing system.*
<https://www.mhlw.go.jp/content/10808000/001276014.pdf>

Rapid Introduction Premium ¹⁵⁸	Applied where an innovative new drug has been introduced promptly into the Japanese market	5-10%
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Drug Price Revisions for Originator Pharmaceuticals

The following provides an overview of price revisions after a pharmaceutical has been listed in the Drug Price Standard.

Drug price revisions are conducted once annually, primarily on the basis of the divergence between market transaction prices and the official reimbursement price.¹⁵⁹

More specifically, the revised drug price is calculated by taking the weighted average of actual transaction prices obtained through nationwide drug price surveys of insured medical institutions, pharmacies, and pharmaceutical wholesalers, and then adding:

- An adjustment margin to ensure stable distribution; and
- Consumption tax.

Seeing as the difference between the official reimbursement price and the actual market price constitutes revenue for medical institutions and pharmacies, the official drug price is revised to a level equal to the weighted average of actual market prices plus a fixed adjustment margin of 2 per cent.¹⁶⁰ In other words, where the divergence between the official drug price and the weighted average market price exceeds 2 per cent, the price is revised by the amount of that difference.

In principle, this revision mechanism exerts downward pressure on pharmaceutical prices. Through this system, the Ministry of Health, Labour and Welfare effectively restrains overall medical expenditure.

In addition to standard annual price revisions, Japan has established supplementary recalculation mechanisms. These are applied in cases where market size has expanded substantially beyond initial projections or patent protection has expired (see the table below).¹⁶¹

Such measures reduce the prices of relevant pharmaceuticals to contain overall healthcare expenditure. At the same time, the system seeks to preserve reasonable profit margins to encourage continued investment in innovative drug development.

Against the backdrop of sustained growth in healthcare expenditure, further reforms to the drug pricing system are anticipated in the future.

¹⁵⁸ This is a premium newly introduced in fiscal year 2024. For further details, see the Ministry of Health, Labour and Welfare, Overview of the Current Drug Pricing System.

¹⁵⁹ Strictly speaking, drug price revisions in odd-numbered fiscal years (so-called interim revisions) were introduced in FY2021. However, compared with the main revisions conducted in even-numbered years, the scope of applicable drug pricing rules was initially limited. In recent years, revisions in odd-numbered fiscal years have increasingly come to approximate the pricing rules applied during the main revisions in even-numbered years (Ministry of Health, Labour and Welfare, 2025). Ministry of Health, Labour and Welfare. (2025). *Drug price revision for FY2025 (reference materials)*. <https://www.mhlw.go.jp/content/10808000/001360022.pdf>

¹⁶⁰ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the current drug pricing system*. <https://www.mhlw.go.jp/content/10808000/001276014.pdf>

¹⁶¹ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the current drug pricing system*. <https://www.mhlw.go.jp/content/10808000/001276014.pdf>

Recalculation Category	Direction Description	Explanation
Additional Price Reduction for Long-Listed Products	Reduction	Applies additional price reductions to long-listed products (off-patent originator drugs). The resulting savings serve as a financial source for price increases designed to promote innovative drug development.
Market Expansion Recalculation	Reduction	Where annual sales significantly exceed projected sales, the drug price is reduced under specified conditions. Products falling within therapeutic areas pre-designated by the Central Social Insurance Medical Council (Chuikyo) are exempt from this recalculation.
Indication Change Recalculation	Reduction	Where the principal indication or therapeutic effect of a pharmaceutical has been changed, and comparable drugs exist for the new primary indication, the price is recalculated so as to align more closely with the price of similar drugs indicated for the revised use.
Dosage and Administration Change Recalculation	Product-Dependent	Where changes are made to the dosage and administration relating to the principal indication, the price is recalculated so that the daily drug cost remains equivalent before and after the revision.
Unprofitable Product Recalculation	Increase	For pharmaceuticals recognized as highly necessary for insured medical care but whose prices are so low that continued manufacture and marketing would be difficult, prices are recalculated using the cost-based method. In such cases, the operating profit margin is capped at 5 per cent.
Premium for Promotion of New Drug Creation and Resolution of Off-Label Use	Increase	To promote the creation of innovative new drugs and address drug lag/loss, scheduled price reductions based on market transaction prices may be deferred. Application requires fulfilment of both corporate eligibility criteria and product-specific requirements.

In addition, since 2019, a cost-effectiveness evaluation system has been introduced.

This system primarily targets pharmaceuticals and medical devices with a large market scale or exceptionally high unit prices and adjusts a portion of their reimbursement prices from the perspective of balancing costs and clinical effectiveness.

5.3 Pharmaceuticals and Medical Devices | Generic Medicines

Definition of Generic Medicines

Generic medicines are defined as pharmaceutical products that are approved after the expiry of the patent of an originator (brand-name) drug, and which contain the same active ingredients and specifications as the originator, having been demonstrated to be therapeutically equivalent.

Originator medicines are granted a period of market exclusivity under the patent system, including both the duration of patent protection and the re-examination period during which their efficacy and safety are evaluated. Once this period has expired, applications for the approval and subsequent marketing of generic medicines become permissible.

While generic medicines are, in principle, identical to originator medicines in terms of indications, dosage, and administration, they are characterized by significantly lower prices. Furthermore, whereas originator medicines are typically manufactured and marketed exclusively by the original developer, generic medicines are often produced and distributed by multiple manufacturers.¹⁶²

Approval of Generic Medicines

Unlike originator medicines, the manufacture and marketing of generic medicines do not require the conduct of full clinical trials to verify efficacy and safety. However, even when medicines contain the same active ingredients, differences in manufacturing processes may affect their performance. Therefore, regulatory authorities assess whether generic medicines are equivalent to originator medicines in terms of efficacy and safety.

The approval process primarily focuses on three key elements: specifications and test methods, stability testing, and bioequivalence studies. If these assessments demonstrate equivalence with the originator product, the generic medicine is deemed to meet the required standards of efficacy and safety and is subsequently approved.

In recent years, cases of misconduct relating to approval of application data, as well as quality issues arising from deficiencies in manufacturing and quality control systems, have attracted significant public attention in relation to generic medicines. Since 2021, new regulatory requirements have been introduced to clarify the responsibilities of applicants and to ensure the reliability of submission data. These include the mandatory submission of documentation explaining the reliability of application data, as well as verification of staffing arrangements and their appropriateness at manufacturing sites.¹⁶³ Careful attention to these requirements is therefore essential.

¹⁶² Against this background, in Europe and the United States, these medicines are commonly referred to as “generic drugs,” as they are more frequently prescribed by their generic (non-proprietary) names, in contrast to originator drugs, which are often identified by brand names. This terminology has also been adopted in Japan, where they are referred to as “generic medicines.”

¹⁶³ Ministry of Health, Labour and Welfare. (2021). *New measures in the approval review process for generic drugs* (Notification No. Yakuseiyaku-Shinsa 0702-7; Yakusei-Kanmaku 0702-7, issued July 2, 2021). <https://www.pmda.go.jp/files/000250546.pdf>

Pricing of Generic Medicines¹⁶⁴

Seeing as generic medicines do not require extensive clinical trials, their research and development costs are substantially lower than those of originator medicines. This enables pharmaceutical companies to set lower prices while still maintaining profitability.

Within Japan's public health insurance system, the reimbursement price of generic medicines is typically set at a significantly lower level, generally 50% or less of the price of the originator medicine. In addition, reimbursement prices are determined with reference to prevailing market prices. Consequently, when multiple generic products containing the same active ingredient are available and price competition arises, this is reflected in the setting of even lower reimbursement prices.

Generic medicines are listed on the National Health Insurance drug price list twice annually (in June and December). When a generic medicine is first listed, its price is generally set at 50% of the originator medicine's price, subject to two exceptions:

- For oral medicines, if the number of products seeking listing exceeds ten, the price is set at 40% of the originator medicine's price.
- For biosimilars, the price is set at 70% of the originator medicine's price.

If generic medicines have already been listed, newly listed products are priced at the same level as the lowest-priced existing generic.

Furthermore, after initial listing, drug prices are gradually reduced through annual revisions based on changes in actual market prices. In cases where multiple generic medicines exist, a system is applied in which products are grouped into price bands, and a single weighted average price is assigned within each band:

- Products priced below 30% of the highest price are grouped into one price category (weighted average)
- Products priced between 30% and below 50% of the highest price are grouped into another category
- Products priced at 50% or above are grouped into a separate category

In recent years, additional measures have been introduced to reduce price variation, including consolidating products into a single price band in principle after 12 years from listing, and preventing price increases resulting from such consolidation. These measures are designed to ensure a continued downward trend in prices.

Prescription and Dispensing of Generic Medicines

As noted above, the MHLW has actively promoted the use of generic medicines through policy targets. Under Japan's public health insurance system, physicians are, in principle, required to prescribe

¹⁶⁴ This section summarises the key aspects of price revisions for generic drugs, based on the Ministry of Health, Labour and Welfare's *Drug Price Revision for FY2024 (4): Generic Drugs and Long-Listed Drugs* (Ministry of Health, Labour and Welfare, 2024).

medicines using their generic (non-proprietary) names.

Pharmacies are encouraged to dispense generic medicines, provided that there are no specific instructions from the prescribing physician after obtaining patient consent. Incentive schemes have also been introduced for pharmacies that actively dispense generic medicines.

However, physicians retain the authority to specify that substitution with a generic medicine should not occur, by signing or otherwise indicating this on the prescription.

A comparable system is observed in France, where patients who refuse substitution with generic medicines must pay the full cost at the pharmacy and subsequently apply for reimbursement, thereby strongly encouraging the use of generics.

By contrast, a different system operates in United States, where the range of medicines available is determined by the patient's insurance plan. As a result, physicians and pharmacies have less discretion, and decisions regarding which medicines are covered are negotiated between insurers, such as Health Maintenance Organizations (HMOs), and pharmaceutical companies.

Industrial Policy on Generic Medicines

The Japanese government has adopted a policy of promoting the use of generic medicines in order to sustain the universal health insurance system¹⁶⁵ while ensuring the quality and efficiency of healthcare delivery.

Specifically, in the Cabinet decision of June 2021 (*Basic Policy on Economic and Fiscal Management and Reform 2021*), a target was set to achieve a generic medicine volume share of at least 80% in all prefectures by the end of fiscal year 2023. As of March 2023, 36 prefectures had achieved this target. In addition, a new target based on value share has been established: by the end of fiscal year 2029, the proportion of total expenditure on generic medicines relative to the combined expenditure on generics and originator medicines with generic equivalents is to reach 65%.¹⁶⁶ It is anticipated that policies promoting the use of generic medicines will continue to be strengthened in the coming years.

5.4 Pharmaceuticals and Medical Devices | Over-the-Counter (OTC)

Medicines

Distinction between Prescription Medicines and OTC Medicines

In addition to prescription medicines discussed in Sections 5.2 and 5.3, there exist non-prescription medicines that can be purchased directly by the general public at pharmacies and drugstores and used

¹⁶⁵ As a background factor, Japan's universal health insurance system enables all citizens to receive necessary and high-quality healthcare with a certain level of out-of-pocket payment. However, due to factors such as advances in medical technology and rapid population ageing, healthcare expenditures have continued to rise, placing increasing pressure on healthcare financing and raising concerns about the sustainability of the universal health insurance system.

¹⁶⁶ Ministry of Health, Labour and Welfare. (2024, September 30). *Roadmap for the appropriate use of generic drugs with a focus on ensuring stable supply*. <https://www.mhlw.go.jp/bunya/iryou/kouhatsu-iyaku/dl/roadmap04.pdf>

at their own discretion.¹⁶⁷ These include general sale medicines and pharmacist-guided medicines, which are collectively referred to as over-the-counter (OTC) medicines.

General sale medicines are defined as pharmaceutical products other than prescription medicines (excluding pharmacist-guided medicines). In other words, they are medicines that can be purchased by the general public and used based on individual judgement. In most cases, these products contain ingredients that are considered sufficiently safe for such use.¹⁶⁸

In recent years, Japan has permitted the online sale of general sale medicines. As these products can be selected and used by consumers independently, sellers are legally required to provide appropriate information to purchasers. Based on risk classification, these medicines are categorized into three groups: Class 1, Class 2, and Class 3. Each class has differing levels of required information provision:

- **Class 1 medicines:**

These are medicines for which safety as general sale products has not yet been fully established, or where risks remain uncertain, as well as those that may cause adverse effects that could significantly interfere with daily life.

The provision of information by a pharmacist is mandatory, and these medicines may only be sold or dispensed under the supervision and guidance of a pharmacist.

- **Class 2 medicines:**

These are medicines that may cause side effects that could interfere with daily life. They may be sold under the supervision of either a pharmacist or a registered sales clerk, and the provision of information is required on a best-efforts basis.

- **Class 3 medicines:**

These include all other medicines with relatively low risk.

There are minimal legal requirements for providing product explanations at the point of sale unless specifically requested by the purchaser.

Pharmacist-Guided Medicines

Pharmacist-guided medicines were introduced as a new category following the 2013 revision of the Pharmaceuticals and Medical Devices Act.¹⁶⁹

These medicines may be used at the patient's discretion; however, they require face-to-face guidance and information provision by a pharmacist at the time of sale.

This category includes, for example:

- Medicines that have only recently been switched from prescription to non-prescription status

¹⁶⁷ "OTC" is an abbreviation for "over-the-counter." OTC medicines refer to pharmaceuticals that can be purchased directly by consumers at pharmacies and other retail outlets without a physician's prescription, in contrast to prescription medicines (ethical drugs), which require a doctor's authorization.

¹⁶⁸ Ministry of Health, Labour and Welfare. (2004, September 6). *Comparison between prescription pharmaceuticals and over-the-counter pharmaceuticals*. <https://www.mhlw.go.jp/shingi/2004/09/s0906-6c.html>

¹⁶⁹ Ministry of Health, Labour and Welfare. (n.d.). *Pharmaceuticals requiring guidance*. <https://www.mhlw.go.jp/content/11121000/001062522.pdf>. According to the definition provided by the Ministry of Health, Labour and Welfare, pharmaceuticals requiring guidance are defined as those whose effects on the human body are not considered significant, are intended to be used based on patient choice informed by information provided by pharmacists or other healthcare professionals, and for which appropriate use necessitates face-to-face provision of information and guidance based on pharmaceutical expertise by a pharmacist.

and for which the risk profile as OTC products has not yet been fully established (so-called *recently switched products*),

- Medicines approved directly as OTC products without prior classification as prescription medicines, and
- Potent medicines and other products requiring heightened caution.¹⁷⁰

OTC Medicine Category		Responsible Professional	Information Provision to Customers	Response to Customer Consultation	Online/Mail-order Sales
Pharmacist guided medicines		Pharmacist	Mandatory written information provided through face-to-face consultation.	Mandatory	Not-permitted
General sales Medicine	Class 1		Mandatory written information provision		Permitted
	Class 2	Pharmacist or registered sales clerk	Information provision based on a 'best-effort' basis		
	Class 3		No specific legal requirement		

¹⁷⁰ Ministry of Health, Labour and Welfare. (n.d.). *Pharmaceuticals requiring guidance*. <https://www.mhlw.go.jp/content/11121000/001062522.pdf>. According to the Ministry of Health, Labour and Welfare, pharmaceuticals requiring guidance are categorised into the following groups: (1) new pharmaceuticals that are still within the re-examination period (i.e., products approved directly as over-the-counter medicines without prior classification as prescription drugs); (2) pharmaceuticals switched from prescription to over-the-counter status that are within the post-marketing surveillance period (so-called "just-switched products"); and (3) poisonous drugs and deleterious drugs as defined under Article 44, paragraphs 1 and 2 of the Pharmaceuticals and Medical Devices Act.

5.5

Pharmaceuticals and Medical Devices | Medical Devices

Classification and Approval of Medical Devices¹⁷¹

Medical devices are defined as products whose structure, method of use, efficacy, or performance is clearly specified, and which are intended either for the diagnosis, treatment, or prevention of disease, or to affect the structure or function of the human body, as stipulated by Cabinet Order¹⁷².

Medical devices are classified into four regulatory classes according to their intended use and level of risk to patient safety. The approval requirements differ depending on the class. In particular, Class III and Class IV devices, which pose higher risks to the human body, require formal review by the Pharmaceuticals and Medical Devices Agency (PMDA).

Regulatory Class		Relevant Medical Devices	Regulatory Requirements
General Medical Devices	Class 1	Devices for which, even in the event of malfunction, the risk to the human body is considered extremely low. - <i>Examples:</i> enteral feeding administration sets, nebulizers, X-ray film, blood gas analyzers, nonwoven surgical materials.	Notification (Self-declaration)
Controlled Medical Devices	Class 2	Devices for which, even in the event of malfunction, the risk to the human body is considered relatively low. - <i>Examples:</i> X-ray imaging systems, electrocardiographs, ultrasound diagnostic equipment, injection needles, blood collection needles, vacuum blood collection tubes, infusion sets for infusion pumps, Foley catheters, hearing aids, home-use massage devices, software-based medical devices.	Third-party certification (for devices with established certification standards)
Specially Controlled Medical Devices	Class 3	Devices for which, in the event of malfunction, the risk to the human body is considered relatively high. - <i>Examples:</i> particle beam therapy systems, hemodialysis devices, epidural catheters, infusion pumps, automated peritoneal dialysis systems, artificial bone, heart–lung machines, ventilators, software-based medical devices.	Review by the Pharmaceuticals and Medical Devices Agency (PMDA) and approval by the

¹⁷¹ Pharmaceuticals and Medical Devices Agency. (n.d.). *Medical devices*. <https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/devices/0028.html>

¹⁷² Article 2, paragraph 4 of the Pharmaceuticals and Medical Devices Act defines “medical devices” as instruments and apparatus (excluding regenerative medicine products) that are intended for use in the diagnosis, treatment, or prevention of diseases in humans or animals, or that are intended to affect the structure or function of the human or animal body, and that are designated by Cabinet Order.

			MHLW ¹⁷³
	Class 4	Devices for which malfunction may pose a high level of invasiveness and a direct risk to life. - <i>Examples:</i> pacemakers, coronary stents, artificial blood vessels, percutaneous transluminal coronary angioplasty (PTCA) catheters, central venous catheters, bioabsorbable fixation screws, software-based medical devices.	Review by the PMDA and approval by the MHLW

Acceleration of Medical Device Approval Processes

In recent years, efforts have been made to accelerate the approval and review processes for medical devices through collaborative initiatives between the MHLW and manufacturers. Several key policy frameworks have been introduced:

- In 2019, the government established the *Collaborative Plan for the Optimization of Medical Device Regulation and Review*, alongside a similar framework for in vitro diagnostics. These initiatives aimed to streamline development processes, reduce the “development lag” prior to regulatory submission, and promote greater international regulatory harmonization.
- Amendments to the Pharmaceuticals and Medical Devices Act (PMD Act) in 2019 introduced a fast-track approval system for adaptive medical devices, such as those incorporating artificial intelligence (AI), whose performance may evolve post-market. Under this system, certain modifications to approved specifications are permitted within predefined parameters.
- In 2021, the *DASH for SaMD (Digital Transformation Action Strategies in Healthcare for Software as a Medical Device)* initiative was launched, establishing dedicated consultation frameworks within both the MHLW and PMDA to support innovation and regulatory navigation.
- In 2023, the updated *DASH for SaMD 2* strategy was introduced. This framework further promotes early identification of innovative technologies, transparency in regulatory evaluation criteria, the introduction of two-stage approval pathways, strengthened PMDA consultation services, and support for international market expansion.

Insurance Reimbursement for Medical Devices¹⁷⁴

Unlike pharmaceuticals, not all approved medical devices are automatically covered under the public health insurance system. To qualify for reimbursement, devices must be designated as insured medical materials.

These materials are categorized within the reimbursement framework as either:

¹⁷³ Since 25 November 2014, certain Class III high-risk medical devices for which certification standards have been established have become eligible for certification by third-party certification bodies.

¹⁷⁴ Ministry of Health, Labour and Welfare. (2024). *Outline of the FY2024 reform of the health insurance system for medical materials (reference materials)*. <https://www.mhlw.go.jp/content/12404000/001180647.pdf>

- Specified treatment materials¹⁷⁵ which are reimbursed separately; or
- Materials included within technical fees, where costs are incorporated into broader service payments¹⁷⁶

The reimbursement status and pricing of a device depend on its classification within the following evaluation categories, determined after regulatory approval through submission of an application for insurance listing, followed by review by expert committees and the Central Social Insurance Medical Council (Chuikyo):

- A1 (Comprehensive), A2 (Special Comprehensive), and A3 (Existing Technology with Modifications)
→ The cost of the device is included within the medical service fee; separate reimbursement is not permitted.
- B1 (Existing Functional Category), B2 (Modified Existing Category), and B3 (Time-limited Improvement Premium)
→ These are classified as specified insured medical materials, with set reimbursement prices based on functional categories. Costs can be claimed separately from service fees.
- C1 (New Function) and C2 (New Function and New Technology)
→ Similar to B categories, separate reimbursement is permitted. However, these categories require the establishment of new functional classifications, and in the case of C2, the associated medical procedure must also be newly listed within the reimbursement schedule.

Medical devices classified under B3, C1, and C2 require formal approval by the Central Social Insurance Medical Council.

Evaluation Categories for Insured Medical Materials		Evaluation Method
A1	Comprehensive	Evaluated comprehensively within existing medical fee schedule items.
A2	Specific and Comprehensive	Evaluated comprehensively within specified existing medical fee schedule items.
A3	Existing Technology with Modifications	The technology utilizing the product is evaluated within existing medical fee schedule items, with accompanying revisions to

¹⁷⁵ Central Social Insurance Medical Council. (n.d.). *Report on the evaluation of specified insurance medical materials*. <https://www.ipss.go.jp/publication/j/shiryou/no.13/data/shiryou/iryou/603.pdf> According to the Central Social Insurance Medical Council, specified treatment materials refer to items related to (1) medical fee schedules (including those for the elderly), (2) dental fee schedules (including those for the elderly), and (3) dispensing fee schedules (including those for the elderly).

¹⁷⁶ Pharmaceuticals and Medical Devices Agency. (n.d.). *Health insurance coverage for medical devices*. <https://www.pmda.go.jp/files/000273983.pdf>

		conditions or notes.
B1	Existing Functional Category	Evaluated according to an existing functional category, with reimbursement provided separately from the technical fee.
B2	Existing Functional Category with Modifications	Evaluated according to an existing functional category, with separate reimbursement from the technical fee, accompanied by modifications to the definition of the functional category or related criteria.
B3	Time-limited Improvement Premium	Evaluated by applying a temporary premium to an existing functional category.
C1	New Function	Requires the establishment of a new functional category, while the associated medical technology has already been evaluated.
C2	New Function and New Technology	The medical technology utilizing the product has not yet been evaluated.
R	Refurbished/Reprocessed Products	Products Evaluated under a newly established functional category specific to reprocessed products.
F	Unsuitable for Insurance Coverage	-

Pricing of Newly Listed Medical Materials¹⁷⁷

Specified insured medical materials are assigned reimbursement prices according to functional categories, a system referred to as “listing by functional classification.”¹⁷⁸ Within each functional category, all products are assigned a uniform reimbursement price.

The reimbursement price for newly listed medical materials is determined using one of two approaches:

- The comparative method based on similar functional categories, where an appropriate comparator exists; or
- The cost accounting method, where no comparable category is available.

These prices are revised in conjunction with broader revisions to the medical fee schedule and pharmaceutical pricing.¹⁷⁹

¹⁷⁷ Ministry of Health, Labour and Welfare. (n.d.). *Overview of the health insurance system for medical materials*. <https://www.mhlw.go.jp/content/10808000/001508753.pdf>

¹⁷⁸ As outlined in Sections 5.2 and 5.3, prescription pharmaceuticals are assigned reimbursement prices on a product-by-product basis; therefore, it is important to note that the framework for determining reimbursement prices differs from that applied to medical materials.

¹⁷⁹ Ministry of Health, Labour and Welfare. (2016). *Overview of the FY2016 reform of the health insurance system for medical materials*. <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000114377.pdf>

In parallel with pharmaceutical pricing policy, a system of premium adjustments has been introduced. This mechanism is designed to encourage highly innovative technologies while restraining prices for products assessed as having limited added value. Furthermore, foreign average price adjustments¹⁸⁰ are applied to ensure fair market competition.

Revisions to standard material prices are, as with pharmaceuticals, based on the discrepancy between official reimbursement prices and actual market transaction prices. In principle, the revised price is calculated by adding a fixed margin (typically 4%) to the market price inclusive of consumption tax, with the condition that it does not exceed the pre-revision reimbursement level.¹⁸¹

The MHLW has also introduced several mechanisms to appropriately recognize and reward innovation:

- **Challenge Application System:**
Allows for re-evaluation of a product's classification into a new functional category after listing, based on accumulated real-world usage data.
- **Time-limited Improvement Premium:**
Applies a temporary price premium to products that may replace existing listed items within the same functional category, valid until two revision cycles have elapsed following initial listing.
- **Exceptional Functional Classification Measures:**
For highly innovative products or those designated under priority review schemes, separate pricing adjustments are maintained independently from existing products for a defined period, thereby preventing downward price pressure from subsequently listed products in the same category.

Since 2019, a cost-effectiveness-based pricing adjustment system has been introduced for medical devices, analogous to that applied to pharmaceuticals, to enable more appropriate reimbursement pricing.

This system applies to products with large market size, or significantly high unit cost.

Importantly, cost-effectiveness evaluation is used not to determine whether a product is reimbursed, but rather to adjust its price after reimbursement has already been granted.¹⁸² Currently, in line with government policy, discussions are ongoing within advisory bodies of the Ministry of Health, Labour and Welfare regarding the expanded application of cost-effectiveness evaluation. These discussions aim to balance the promotion of innovation, sustainability of rapid reimbursement decisions, and the

¹⁸⁰ Ministry of Health, Labour and Welfare. (2024). *Overview of the FY2024 reform of the health insurance system for medical materials*. <https://www.mhlw.go.jp/content/12400000/001251540.pdf> Since the FY2024 reform of the health insurance system for medical materials, a recalculation mechanism has been applied whereby reimbursement prices are subject to revision when they exceed the average foreign price by a certain margin; under this mechanism, the reference levels for foreign price adjustments used in the recalculation process have also been established (Ministry of Health, Labour and Welfare, 2024).

¹⁸¹ Ministry of Health, Labour and Welfare. (2024). *Overview of the FY2024 reform of the health insurance system for medical materials*. <https://www.mhlw.go.jp/content/12400000/001251540.pdf>

¹⁸² Ministry of Health, Labour and Welfare. (2024). *Overview of the FY2024 revision of medical fees: Cost-effectiveness evaluation system*. <https://www.mhlw.go.jp/content/12400000/001251541.pdf>

financial burden on the insured population, particularly the working-age group.¹⁸³

Industrial Policy for Medical Devices

The medical device industry is widely regarded as a key growth sector in advanced economies, and Japan is no exception.

While Japan holds a strong global market position in certain areas, such as endoscopic and diagnostic imaging technologies, it faces challenges in other segments of the industry. In response, the Japanese government formulated a Basic Plan for the Promotion of Research, Development, and Dissemination of Medical Devices in 2016.¹⁸⁴

In 2022, a second-phase plan was adopted, incorporating lessons from the COVID-19 pandemic, particularly the need to ensure stable supply chains.¹⁸⁵

Based on these policy frameworks, a range of initiatives and programs have been implemented to support the development and expansion of the medical device industry.

¹⁸³ Ministry of Health, Labour and Welfare. (n.d.). *Central Social Insurance Medical Council: Cost-effectiveness Evaluation Subcommittee*. https://www.mhlw.go.jp/stf/shingi/shingi-chuo_128159.html

¹⁸⁴ Cabinet Secretariat. (n.d.). *Basic plan for the promotion of research, development, and dissemination of medical devices to improve the quality of healthcare received by the public (overview)*. <https://www.kantei.go.jp/jp/singi/kenkouryou/kaihatsu/dai4/sankou1.pdf>

¹⁸⁵ Ministry of Health, Labour and Welfare. (n.d.). *Revision of the basic plan for the promotion of research, development, and dissemination of medical devices to improve the quality of healthcare received by the public*. https://www.mhlw.go.jp/stf/newpage_25953.html

Japanese Health Policy

6. Budgeting

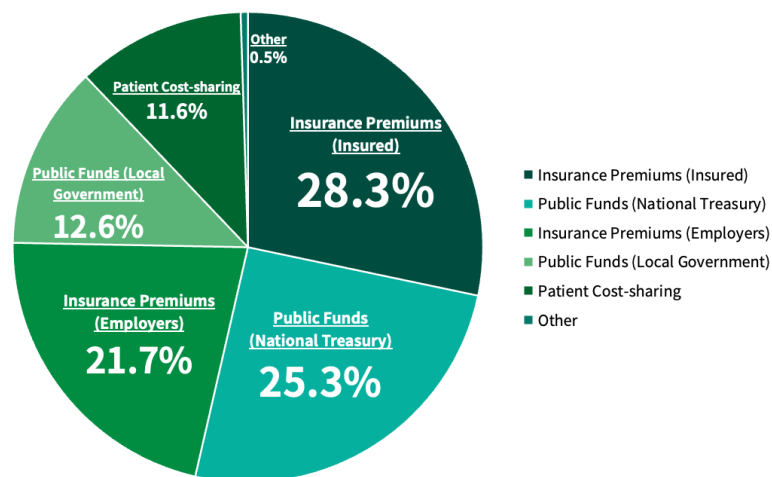
September 2026

6.1

Budgeting | Background

First, we consider the background context in which the budgeting (expenditure control) of medical costs in Japan has become necessary. Japan's public healthcare system is nominally based on a social insurance model; however, in practice, approximately 40 per cent of national healthcare expenditure is financed through taxation, amounting to over ¥15 trillion in total spending. Of this, the ratio between central and local government contributions is roughly 2:1.

Figure 6-1-1 Breakdown of the Sources of Funding for National Healthcare Expenditure (2022)

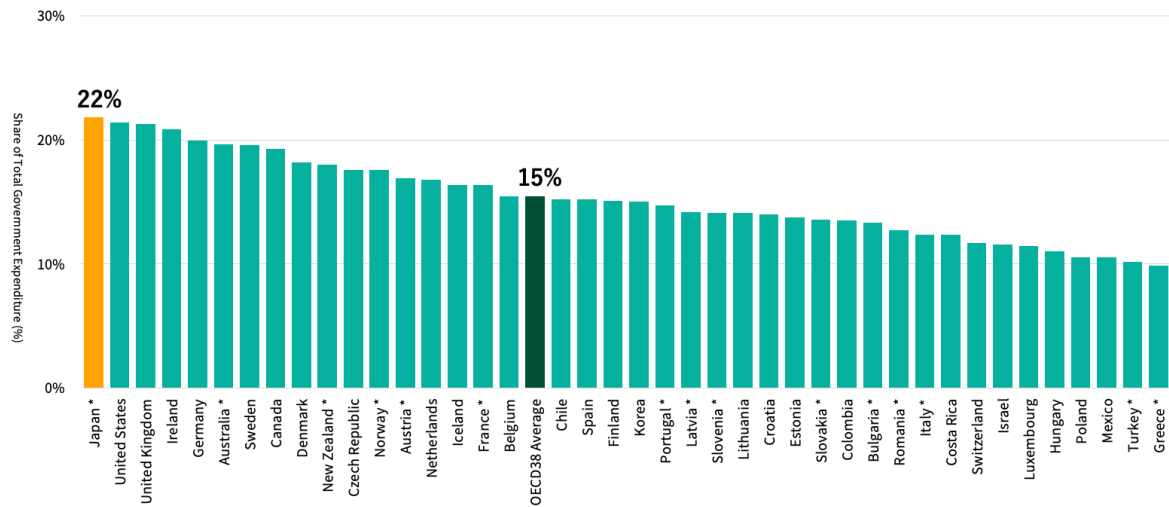


Note: Other cases are subject to the polluter pays principle (under the Act on Compensation for Health Damage Caused by Pollution, relief benefits under the Health Damage Relief Scheme, and automatic

Source: Ministry of Health, Labour and Welfare. 'Overview of National Medical Expenditure for Fiscal Year 2022' <https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/22/dl/data.pdf>

The significant share of healthcare costs within government budgets constitutes one of the key drivers of the strong demand for expenditure control in Japan. The level of public health expenditure as a proportion of total government spending is the highest among OECD member states. Whilst this does, in one sense, reflect the elevated level of healthcare expenditure, it is important to note that other factors also warrant consideration. The first is the comparatively small size of Japan's government. Japan's national burden rate remains modest by international standards, even after accounting for the fiscal deficit, meaning that healthcare expenditure commands a disproportionately large share of a relatively constrained national budget. The second factor is the high proportion of public expenditure within total healthcare spending. In certain other countries, rather than a directly government-provided system such as the United Kingdom's National Health Service or Japan's social insurance model, there exist mechanisms that legally mandate enrolment in private health insurance. As a consequence, even where total healthcare expenditure is high, the share of such expenditure within government budgets may be comparatively low.

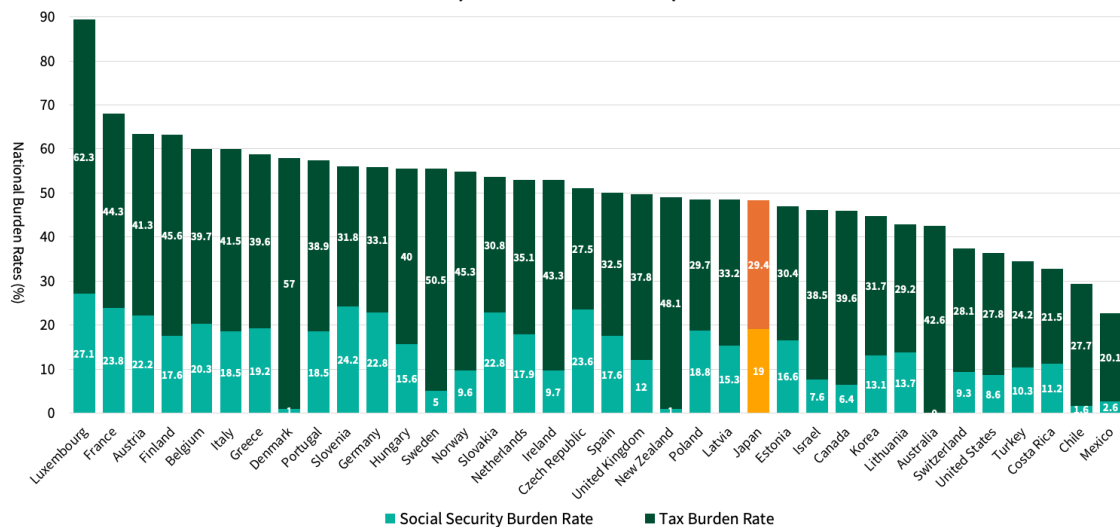
Figure 6-1-2 Proportion of Total Government Expenditure accounted for by Healthcare Expenditure (2021)



Note: Public expenditure is calculated using expenditure under government schemes and social health insurance.

Source : OECD Health Statistics 2023, OECD National Accounts database. https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/11/health-at-a-glance-2023_e04f8239/7a7afb35-en.pdf

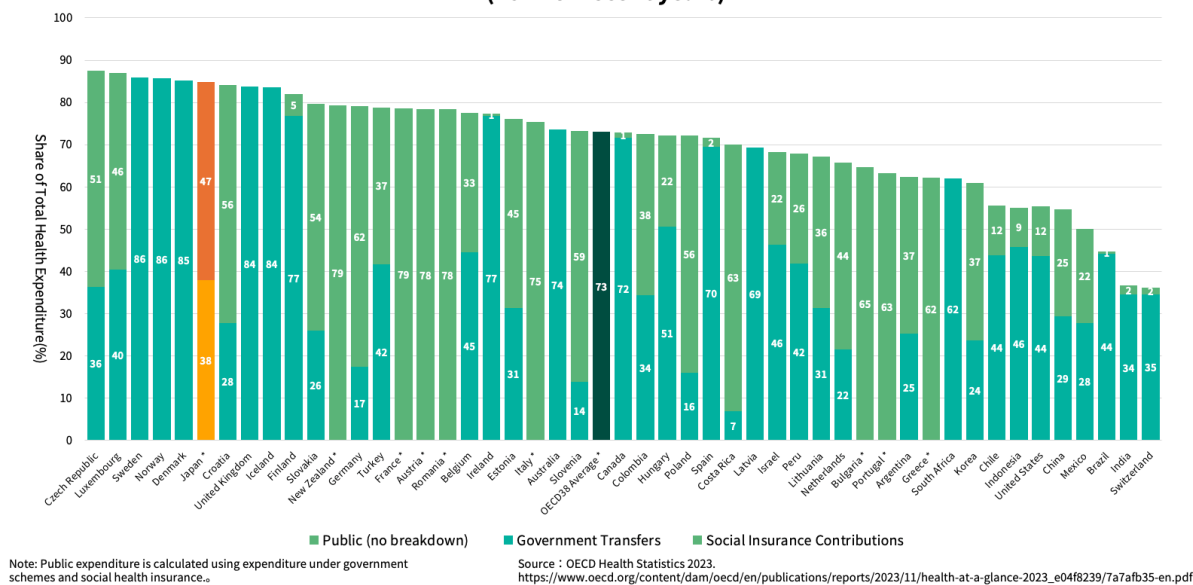
Figure 6-1-3 International Comparison of the Tax-to-GDP Ratio (36 OECD Countries)



Note: 36 out of 38 OECD member countries. The figure for Australia is a provisional estimate. Figures for all other countries are actual values. Data for Colombia and Iceland are not included as national income figures are unavailable.
Note 2: Data from 2022 is used, except for Turkey, for which data from 2017 is used.

Source: Japan: Cabinet Office, 'National Accounts', etc.; Other countries: OECD, 'National Accounts' and 'Revenue Statistics'; US Department of Commerce, Bureau of Economic Analysis

Figure 6-1-4 Proportion of Public Funding in Total Health Expenditure (2021 or recent years)

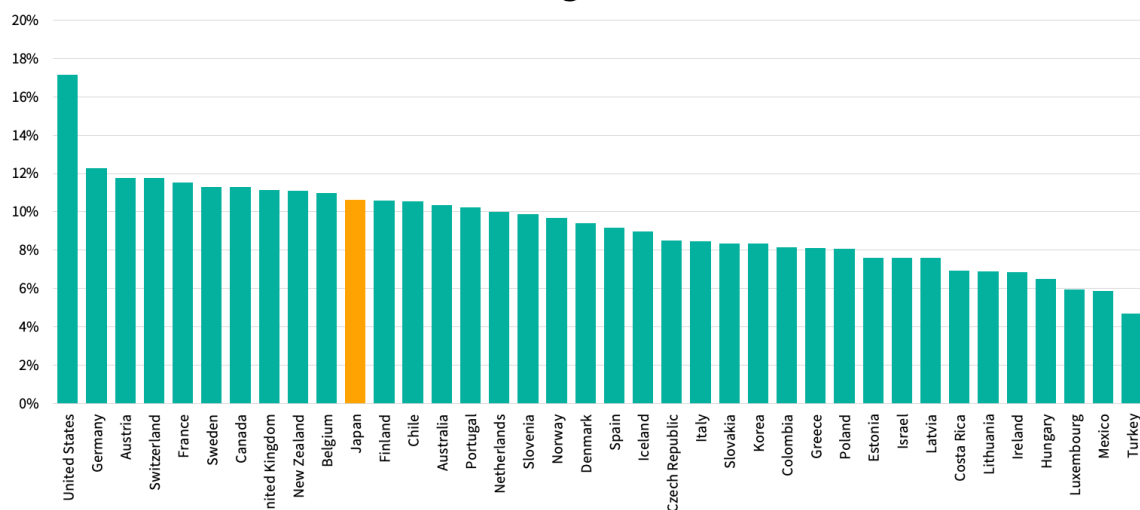


It should be noted that multiple indicators exist for measuring healthcare expenditure, and care must be taken in their application. "National Healthcare Expenditure" (Kokumin Iryohi) is an estimate of the costs incurred at medical institutions for the treatment of illnesses and injuries covered under public health insurance within a given financial year; it does not encompass medical procedures not covered by insurance, nor supplementary room charges. "Total Healthcare Expenditure" (So Hoken Iryo Shishutsu), by contrast, is an indicator calculated on the basis of the OECD System of Health Accounts (SHA) methodology, designed to capture comprehensively all domestic expenditure on health and medical care. Specifically, it includes a portion of long-term care expenditure, payments from private health insurance, maternity and delivery costs, and preventive care expenditure, in addition to medical costs. National Healthcare Expenditure is a government statistical measure of high reliability and is frequently used domestically as an indicator of social security spending; however, as it is based on Japan-specific criteria, its comparability across international contexts is limited. Total Healthcare Expenditure, being based on international standards, offers comparatively greater scope for international comparison, though its estimation methodology remains under development and its calculation process lacks full transparency. In this chapter, Total Healthcare Expenditure is used where international comparisons are made; in all other cases, National Healthcare Expenditure is employed as the principal indicator.

6.2 Budgeting | Macro Level 1

This section examines overall trends in Japan's national healthcare expenditure. As of 2024, Japan's total healthcare expenditure as a proportion of GDP stands at approximately 10.6 per cent, placing Japan eleventh globally. Among other countries, the United States is a considerable outlier at 17.2 per cent, while most other high-ranking nations cluster above the 10 per cent mark.¹⁸⁶ In the United States, in particular, a marked increase has been observed since the 1980s. Furthermore, at a global level, a long-term upward trend in total healthcare expenditure as a proportion of GDP is discernible. It should be noted that the OECD Health Statistics indicator is broader in scope than National Healthcare Expenditure, encompassing over-the-counter medicines, long-term care services, preventive care (including vaccinations and health check-ups), natural deliveries, and supplementary room charges.

Figure 6-2-1 International Comparison of Healthcare Expenditure as a Percentage of GDP (2024)



Note: Health expenditure in this context refers to final consumption of health-related goods and services. This includes health services for individuals (treatment, rehabilitation, long-term care, ancillary services, medical products, etc.) and services for the population (prevention, public health, health administration, etc.), but excludes capital expenditure.

Source : OECD. "Health spending"
<https://www.oecd.org/en/data/indicators/health-spending.html>

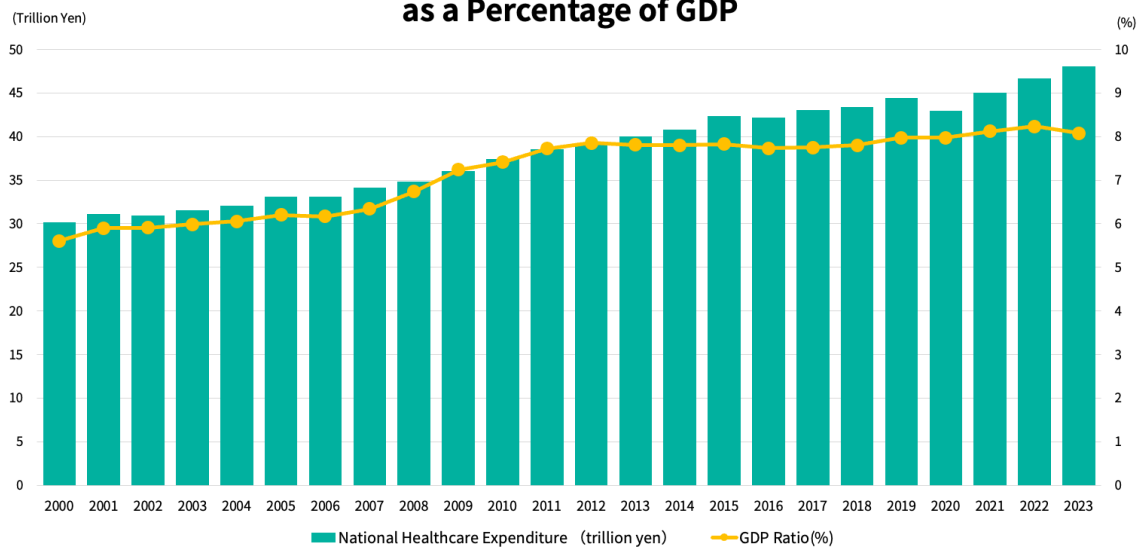
Factors Driving Growth in National Healthcare Expenditure

As the figures demonstrate, national healthcare expenditure has increased year on year. The following table sets out trends in national healthcare expenditure over the most recent five-year period, together with a breakdown of contributing factors. These data indicate that healthcare costs have risen primarily as a result of population ageing and advances in medical technology. With respect to population ageing in particular, in 2022 approximately 60 per cent of national healthcare

¹⁸⁶ OECD. 2024. "Health spending: OECD Indicators."
<https://www.oecd.org/en/data/indicators/health-spending.html>

expenditure was attributable to individuals aged 65 and over¹⁸⁷ (who constituted approximately 29.0 per cent of the total population as of 1 October 2021).¹⁸⁸ On a per capita basis, national healthcare expenditure for those aged 65 and over is approximately four times that of those under 65. As the total population declines, the proportion of older people continues to rise; by 2037, it is projected that individuals aged 65 and over will account for 33.3 per cent of the population, meaning one in every three persons will be in this age group.¹⁸⁹ A further increase in national healthcare expenditure is therefore anticipated.

Figure 6-2-2 Annual Trends in National Healthcare Expenditure as a Percentage of GDP



Note: Gross Domestic Product (GDP) is based on the Cabinet Office's 'National Accounts'.

Source: Overview of National Medical Expenditure for the 2023 Financial Year
<https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/23/dl/R05kekka.pdf>

¹⁸⁷ Ministry of Health, Labour and Welfare. "Overview of National Healthcare Expenditure, FY2022." <https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/22/dl/data.pdf>

¹⁸⁸ Cabinet Office. "Annual Report on the Aging Society, FY2023." https://www8.cao.go.jp/kourei/whitepaper/w-2023/zenbun/pdf/1s1s_01.pdf

¹⁸⁹ Cabinet Office. "Annual Report on the Aging Society, FY2025." https://www8.cao.go.jp/kourei/whitepaper/w-2025/zenbun/pdf/1s1s_01.pdf

Table 6-2-1 Breakdown of the Factors Contributing to the Rise in National Healthcare Expenditure

		2019	2020	2021	2022	2023
Healthcare Expenditure Growth Rate %		2.30%	-3.20%	4.80%	3.70%	2.9% (Note 1)
Impact of Demographic Trends	Population Growth Impact	-0.20%	-0.30%	-0.50%	-0.40%	-0.50%
	Impact of the Ageing Population	1.00%	1.00%	1.10%	0.90%	0.7% (Note 2)
Institutional and Social Impacts	Revision to Medical Fees	-0.07% (Note)	-0.46% (Note)	-0.9% (Note 5)	-0.94%	-0.64% (Note 6)
	Other (not listed above) • Advances in medical care • Review of patient contributions, etc.	1.60%	-3.50%	5.10%	4.20%	3.30%

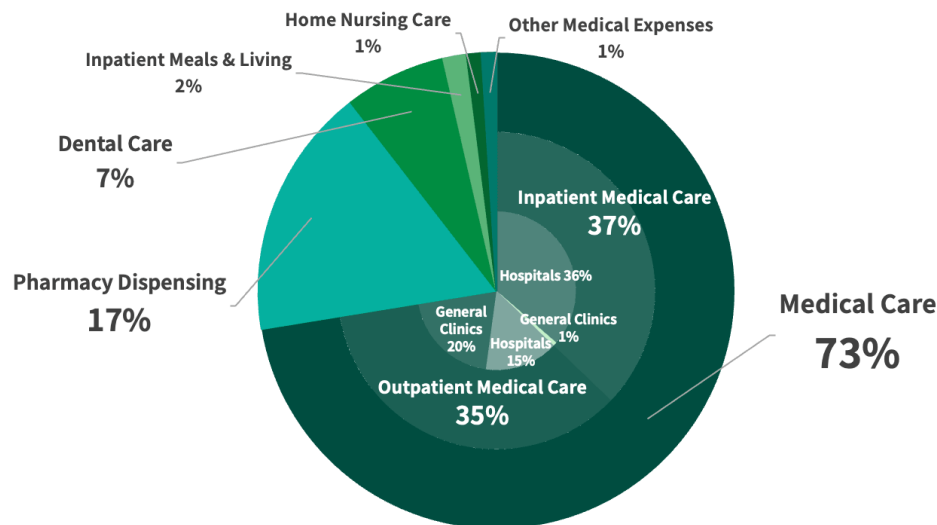
Note: For further details on the figures, please refer to the source data.

Source: Ministry of Health, Labour and Welfare, 'Trends in Medical Expenditure' https://www.mhlw.go.jp/content/doukou_r04.pdf

When national healthcare expenditure is further disaggregated by type of treatment, inpatient medical costs account for the largest share at approximately 37 per cent of total national healthcare expenditure, followed by outpatient medical costs at approximately 35 per cent, and pharmacy dispensing costs at approximately 17 per cent.¹⁹⁰ As noted in Section 4, the comparatively lengthy average length of hospital stay, when set against international comparators, has been identified as a structural factor contributing to the persistently elevated level of inpatient medical costs.

¹⁹⁰ Ministry of Health, Labour and Welfare. "Overview of National Healthcare Expenditure, FY2022." <https://www.mhlw.go.jp/toukei/saikin/hw/k-iryohi/22/dl/data.pdf>

**Figure 6-2-3 Breakdown of National Healthcare Expenditure by Type
(Financial Year 2022)**



Source: Overview of National Medical Expenditure for the 2022 Financial Year
<https://www.mhlw.go.jp/toukei/saikin/hw/k-iryoh/22/dl/data.pdf>

There is no mechanism in Japan for directly controlling the aggregate level of national healthcare expenditure. However, indirect management is exercised through the revision rate applied to fee schedules. This rate is an indicator that estimates the extent to which healthcare expenditure will increase as a result of biennial fee schedule revisions.

The revision rate R at a given point k is expressed by the following formula:

$$R + 1 = \frac{\sum_i p_{k,i} \cdot q_{k-1,i}}{\sum_i p_{k-1,i} \cdot q_{k-1,i}}$$

Here, for each individual fee schedule unit i (representing a specific medical procedure), p denotes the unit price and q the number of claims. In the calculation, p is updated to reflect the revised fee schedule, whilst q is held constant at the preceding period's figure. The revision rate therefore represents the percentage change in expenditure following revision compared to pre-revision levels, assuming identical demand. Accordingly, even where the revision rate is zero per cent, expenditure may still increase due to the q component, for instance, through population ageing or increased consultation frequency.¹⁹¹

As noted in Section 2, the revision rate was, until the early 2000s, determined by the Central Social Insurance Medical Council (Chuikyo). It is now determined by the Cabinet, meaning that top-down aggregate management of total healthcare expenditure is exercised, albeit indirectly.

It should be noted, however, that the aggregate level of healthcare expenditure also results from the bottom-up accumulation of individual medical acts. Excessive top-down management therefore risks rendering healthcare institutions financially unviable. Aggregate expenditure is thus managed within the competing pressures of national fiscal conditions and the financial sustainability of medical institutions.

¹⁹¹ Endo, Hisao. "The Process of Determining Fee Schedules." *Journal of the Japanese Society of Internal Medicine*, Vol. 103, No. 12, pp. 2892–2898.

6.3 Budgeting | Macro Level 2: Financial Management of Medical

Institutions

The patient co-payments collected by medical institutions, together with the balance of fees claimed through and reimbursed by claims review bodies, constitute the revenue of those institutions. Fee schedule reimbursements do not accrue directly as physician income; rather, in the case of clinics and hospitals, they must cover personnel costs for physicians and nurses, expenditure on pharmaceuticals and medical materials, and the costs of maintaining facilities.

Key Statistical Data on Medical Institutions

The Survey of Medical Economic Conditions (Iryo Keizai Jittai Chosa), conducted by the MHLW clarifies the operational and financial conditions of hospitals, general clinics, dental clinics, and dispensing pharmacies. Conducted biennially, it serves as fundamental reference material for the next fee schedule revision. It should be noted that direct comparison between pre-revision conditions across survey cycles is not possible, as the cohort of surveyed institutions changes; furthermore, as a sample survey, the composition of respondents may diverge from the actual distribution of medical institutions.

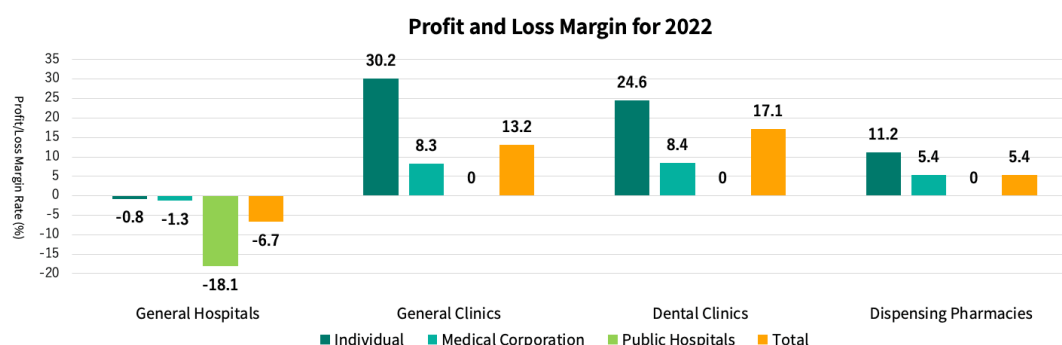
The profit/loss margin rate by institution type and operator is presented in Figure 6-3-1. In FY2022, the profit/loss rate for general hospitals, excluding COVID-related subsidies, stood at –6.7 per cent across all general hospitals (including public institutions), and at –1.3 per cent for medical corporation-operated hospitals. For public institutions alone, the figure was –18.1 per cent, indicating particularly poor profitability.^{192, 193} The overall deterioration in profitability may be attributed to increases in personnel and pharmaceutical expenditure outpacing growth in operating revenues.

¹⁹² Ministry of Health, Labour and Welfare. "Report of the 24th Survey of Medical Economic Conditions." https://www.mhlw.go.jp/bunya/iryouhoken/database/zenpan/jittaityousa/dl/24_houkoku_iryokikan.pdf

¹⁹³ The profit/loss rate is defined as (medical/long-term care revenue – medical/long-term care costs) ÷ (medical/long-term care revenue). See: Ministry of Health, Labour and Welfare. "Circumstances Surrounding Medical Institutions." <https://www.mhlw.go.jp/content/10808000/001479599.pdf>

Figure 6-3-1 Profit and Loss Margin by Type of Healthcare Facility and Operator (Financial Years 2021–2022)

Year	General Hospital				General Clinic			Dental Clinic			Dispensing Pharmacies		
	Individual	Medical Corporation	Public Hospitals	Total	Individual	Medical Corporation	Total	Individual	Medical Corporation	Total	Individual	Medical Corporation	Total
2021	1.4	-0.2	-17.7	-5.5	27.9	7.1	11.8	24.9	9	17.7	10.4	5.7	5.8
2022	-0.8	-1.3	-18.1	-6.7	30.2	8.3	13.2	24.6	8.4	17.1	11.2	5.4	5.4



Note 1: The profit/loss margin is calculated as medical revenue + care revenue – medical and care costs. (Excluding COVID-19-related subsidies)

Note 2: For general hospitals, the figures are based on the aggregate of medical institutions where nursing care revenue accounts for less than 2% of total medical and nursing care revenue; for all others, the figures are based on the aggregate of all medical institutions that responded to the survey, including those filing blue-form tax returns.

Note 3: General hospitals refer to hospitals excluding psychiatric hospitals

Note 4: The graph shows the results for the 2022 financial year.

Source: Central Social Insurance Medical Council. "Report on the 24th Survey on the Actual State of Medical Economics (Survey of Medical Institutions, etc.) – Conducted in 2023"
https://www.mhlw.go.jp/bunya/iryouhoken/database/zenpan/jittaityousa/dl/24_houkoku_iryokukan.pdf

Public hospitals provide care in loss-making areas and remote regions, and a certain degree of deficit is offset through tax revenues.¹⁹⁴ Factors contributing to deficits include those inherent to public hospitals, such as continuation of loss-making departments and recruitment constraints, as well as broader social dynamics, including rapid price inflation, population decline, and COVID-19.¹⁹⁵ Public hospitals also exhibit higher ratios of personnel costs, pharmaceutical costs, and depreciation. In light of these circumstances, improvements in operational management, together with conversion of bed functions and downsizing in line with regional medical needs, are being pursued pursuant to the New Public Hospital Reform Guidelines. Medical corporation-operated general clinics, by contrast, recorded a surplus of +8.3 per cent in FY2022.¹⁹⁶

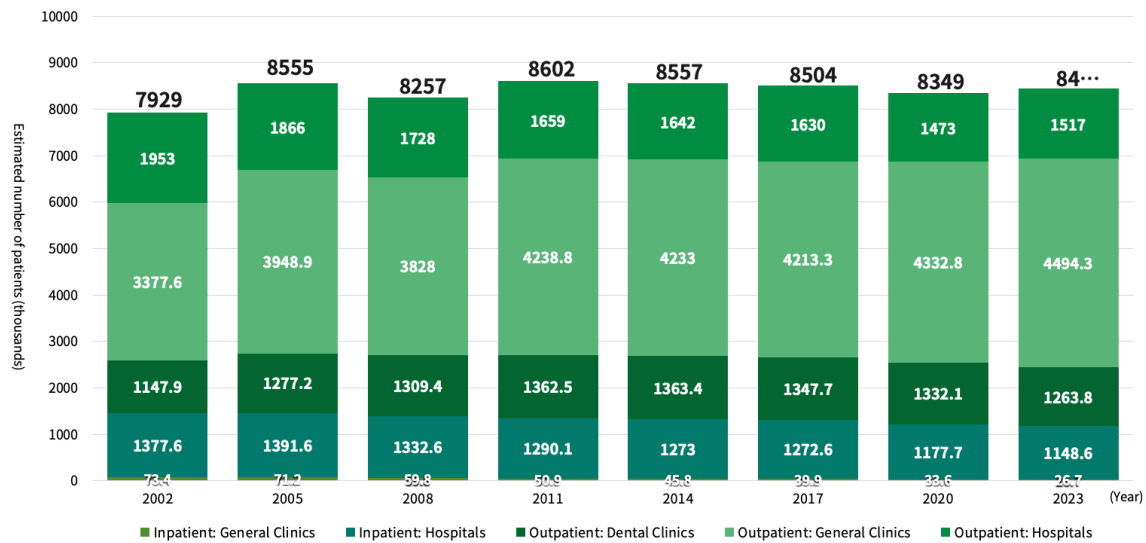
Considering the revenue side: the chart below illustrates annual trends in estimated patient numbers by facility type. In all years, outpatient cases considerably exceed inpatients, a predictable result, given that serious conditions requiring hospitalization occur less frequently. Longitudinally, inpatient numbers have declined since 2008, whilst outpatient numbers have been broadly stable since 2011. The number of patients admitted to general clinics has fallen steadily year on year.

¹⁹⁴ Ministry of Finance. "Supplementary Reference Materials (FY2018 Fee Schedule Revision: 21st Survey of Medical Economic Conditions)." http://www.mof.go.jp/about_mof/councils/fiscal_system_council/sub-of_fiscal_system/proceedings/material/zaiseia291108/01.pdf

¹⁹⁵ Japan Public Health Association. "Report on the Survey on the Management of Public Hospitals, FY2024." https://www.jpaha.or.jp/sub/topics/2025/20250425_2.pdf

¹⁹⁶ Ministry of Health, Labour and Welfare. "Circumstances Surrounding Medical Institutions." <https://www.mhlw.go.jp/content/10808000/001479599.pdf>

Figure 6-3-2 Annual Trends in Estimated Patient Numbers by Type of Facility

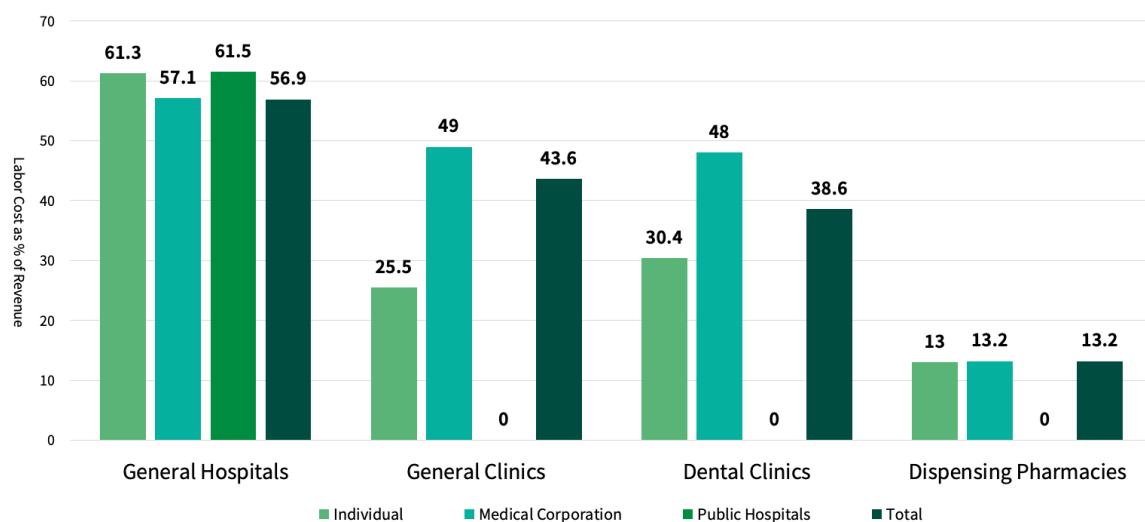


Note: The figures for 2011 exclude the Ishinomaki and Kesennuma medical districts in Miyagi Prefecture and Fukushima Prefecture.

Source : OECD Health Statistics 2023
https://www.oecd.org/content/dam/oecd/en/publications/reports/2023/11/health-at-a-glance-2023_e04f8239/7a7afb35-en.pdf

Turning to the expenditure side: the following chart depicts personnel costs as a proportion of revenue by institution type. The highest figure, observed at general hospitals, indicates that personnel costs account for close to 60 per cent of revenues, representing a significant operational challenge and a primary contributor to the deterioration in profit/loss margins.

Figure 6-3-3 Payroll Costs as a Percentage of Revenue (Financial Year 2022)



Note: Revenue refers to the combined total of medical and care service revenue.

Source: Report on the 24th Survey on the Actual State of the Healthcare Economy (Survey of Medical Institutions, etc.)
https://www.mhlw.go.jp/bunya/iryouhoken/database/zenpan/jittaityousa/dl/24_houkoku_iryokikan.pdf

6.4 Budgeting | Micro Level 1: Incentive-Setting Through Fee

Schedules

The fee schedule (*shinryo hoshu*) refers to the remuneration received by medical institutions and pharmacies for providing services or medicines within the scope of health insurance coverage. Points are assigned to individual insurance-covered medical services, devices, and pharmaceuticals; each institution calculates its reimbursement based on those points and receives payment from the insurer. For the purposes of calculation, one point equals ¥10. The MHLW prescribes all point values and eligibility criteria, and compliance is mandatory for all healthcare providers. Charging in excess of prescribed points is prohibited, and the combined use of insured and non-insured treatment (*kongô shinryô* or "mixed billing") is, as a rule, not permitted. However, certain items are permitted under the Advanced Medical Care Benefit System (*hoken-gai heiyô ryôyô-hi seido*), which encompasses evaluated treatments, patient-initiated treatments, and selected treatments.¹⁹⁷

The fee schedule system comprises two payment methods: fee-for-service and the Diagnosis Procedure Combination (DPC) per-diem payment system. Since the current health insurance system was established in 1961, fee-for-service has been foundational; however, its share has declined with the introduction of DPC. Nevertheless, because surgical procedures, endoscopic examinations, rehabilitative treatments, devices, and pharmaceuticals administered on the day of surgery are excluded from the DPC system, one-third of inpatient hospital revenues continues to be remunerated on a fee-for-service basis.¹⁹⁸ The following provides a detailed explanation of DPC.

It should be noted that the term "DPC" has been used with some ambiguity. During the deliberations preceding the system's establishment, it was observed that the term referred both to: (1) the per-diem lump-sum payment system based on diagnosis group classification; and (2) the patient classification system itself. Originally coined as an acronym for the classification system, DPC (Diagnosis Procedure Combination) does not inherently denote a payment system. Accordingly, "DPC/PDPS (Diagnosis Procedure Combination / Per-Diem Payment System)" was adopted as the formal designation of the payment system. In the following discussion, the abbreviated term "DPC" will be used throughout for the sake of simplicity and in accordance with common usage.

Diagnosis Procedure Combination (DPC) Payment System

DPC is a fee schedule system unique to Japan, introduced in the early 2000s against a backdrop of rising concern about healthcare costs, extended hospitalization periods, increasing demand for medical services, and the sustainability of the system.

¹⁹⁷ Ministry of Health, Labour and Welfare. "The Advanced Medical Care Benefit System." <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/20170925.pdf>

¹⁹⁸ Gerard Anderson and Naoki Ikegami (2011). "How Can Japan's DPC Inpatient Hospital Payment System Be Strengthened? Lessons from the U.S. Medicare Prospective System." Japan-U.S. Health Policy Project, Policy Recommendation Vol. 1. https://hgpi.org/wp-content/uploads/JAPANS%20DPC%20INPATIENT%20HOSPITAL%20PAYMENT%20SYSTEM_JP.pdf

Between 1998 and 2004, a lump-sum payment system for acute inpatient care was piloted at ten national hospitals. The trial revealed that, whilst there was considerable variation in length of stay even for the same condition, a per-diem lump-sum approach produced a smaller discrepancy between lump-sum points and actual treatment costs than an episode-based approach, and that there was an incentive to reduce the per-diem rate. These findings led to the adoption of the current DPC system, in which a per-diem lump-sum fee is calculated in accordance with length of stay.

The principal objective of DPC is to promote the standardization and transparency of medical care. By constructing an objective clinical information database, the aim is to clarify outcomes and areas for improvement, reduce inter-hospital quality disparities, and improve overall standards. Patients benefit from access to objective data on standard treatments and pricing. A reduction in average length of stay is also anticipated. DPC is a lump-sum payment system analogous to the DRG/PPS used in the United States, employing DPC codes constructed primarily on the basis of disease codes and procedures (comprising 3,248 classifications as of April 2024).¹⁹⁹ Key features include a per-diem lump-sum evaluation and the partial incorporation of fee-for-service elements. Reimbursement is on a lump-sum basis for inpatient treatment falling within DPC-designated diagnosis groups, and on a fee-for-service basis for cases that do not.

The Mechanism of Fee Calculation Under DPC

Items subject to the lump-sum evaluation component include the basic hospitalization fee, examinations (including diagnostic imaging), injections, medications, and procedures with a fee schedule value of fewer than 1,000 points, calculated on the basis of per-diem points designated for each DPC classification, length of stay, and institution-specific coefficients. Surgical procedures, radiotherapy, anesthesia, and procedures with a value of 1,000 points or more are excluded from the lump-sum evaluation and reimbursed on a fee-for-service basis.

In recent years, a nationwide review of institution-specific coefficients has been undertaken with the aim of reducing disparities between institutions with equivalent levels of clinical function. Institution-specific coefficients comprise the following:²⁰⁰

Basic Coefficient: A coefficient established to provide an incentive for medical institutions, such as the main campuses of university hospitals, that fulfil functions and roles distinct from those of other facilities.

Function Evaluation Coefficient I: A coefficient that evaluates items applicable to all inpatients (such as the differential for acute inpatient fee rates and supplementary hospitalization charges).

Function Evaluation Coefficient II: A coefficient that evaluates incentives for system-wide efficiency improvements resulting from participation in the DPC/PDPS scheme. It encompasses four sub-components: the efficiency coefficient, complexity coefficient, coverage coefficient, and regional

¹⁹⁹ Ministry of Health, Labour and Welfare. "Overview of the FY2024 Fee Schedule Revision (General Medical Edition)."

<https://www.mhlw.go.jp/content/12400000/001252076.pdf>

²⁰⁰ Ministry of Health, Labour and Welfare. (2024). *Overview of the FY2024 revision of medical fees (medical services overall version)*.

<https://www.mhlw.go.jp/content/12400000/001252076.pdf>

medical coefficient.

Emergency Correction Coefficient: A coefficient that corrects for discrepancies in medical resource inputs during the initial period of hospitalization for emergency inpatients.

Abrupt Change Mitigation Coefficient: A coefficient set for the single financial year of a fee schedule revision, designed to mitigate the impact of sudden changes.

The method of calculation varies according to the stage of hospitalization, with three defined hospitalization periods. The per-diem lump-sum fee for Hospitalization Period I is set at a higher rate than those for Periods II and III. Period II runs from its first day to the mean length of stay; its lump-sum fee, whilst varying by diagnosis group, is lower than Period I in light of average daily resource inputs. Period III is the final defined hospitalization period, with a per-diem fee set lower than Period II.²⁰¹ Where hospitalization extends beyond Period III, the fee schedule is calculated on a fee-for-service basis.

There is ongoing debate as to whether the DPC system is achieving its intended outcomes. When DPC was introduced, cost containment, in addition to shorter average length of stay, was anticipated. Whilst average length of stay has been shortened (see Section 4), analyses have been published suggesting this has not yet directly translated into a reduction in medical costs. It has been pointed out that fee schedule amounts are set on a per-diem rather than a per-episode basis, and that many medical services remain subject to fee-for-service reimbursement. Furthermore, data indicate that whilst average length of stay has fallen, the number of new admissions has increased, and deliberation continues on how to reduce medical costs.²⁰²

6.5 Budgeting | Micro Level 2: Medical Cost Optimization

In order to curb excessive growth in healthcare expenditure driven by rapid population ageing and other factors, a range of medical cost optimization measures has been implemented. One such measure is the Medical Cost Optimization Plan (Iryo-hi Tekisei-ka Keikaku). In accordance with the target objectives and estimation methods set out in the national government's Basic Policy on Medical Cost Optimization, prefectural governments draw up their own Plans.²⁰³

During the First Period (FY2008–2012) and Second Period (FY2013–2017), implemented in five-year cycles, the key objectives were the shortening of average length of hospital stay and improvement in uptake rates for specific health check-ups. In the Third Period (FY2018–2023), in addition to improving specific health check-up uptake, new objectives were incorporated: prevention of

²⁰¹ Ministry of Health, Labour and Welfare. "Response under the DPC System towards the FY2018 Fee Schedule Revision (Draft)." <http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000186975.pdf>

²⁰² Gerard Anderson and Naoki Ikegami (2011). "How Can Japan's DPC Inpatient Hospital Payment System Be Strengthened? Lessons from the U.S. Medicare Prospective System." Japan-U.S. Health Policy Project, Policy Recommendation Vol. 1. https://hgpi.org/wp-content/uploads/JAPANS%20DPC%20INPATIENT%20HOSPITAL%20PAYMENT%20SYSTEM_JP.pdf

²⁰³ Ministry of Health, Labour and Welfare. "Revision of the Basic Policy on Medical Cost Optimization and Medical Cost Optimization Plans." <http://www.mhlw.go.jp/file/05-Shingikai-12401000-Hokenkyoku-Soumuka/0000148008.pdf>

deterioration of diabetes, promotion of generic medicine use, and appropriate use of medicines (optimization of duplicate prescribing and polypharmacy). Inpatient medical costs were to be estimated reflecting the outcomes of promoting differentiation and integration of bed functions. In the Fourth Period (FY2024–2029), new objectives were added: effective and efficient provision of medical and long-term care for elderly persons with complex needs, and effective and efficient utilization of medical resources. The effective promotion of measures through digital technologies was also specified, as was the establishment of coordination mechanisms between prefectural governments and relevant stakeholders.²⁰⁴

Promotion of Generic Medicine Use

Since 2007, Japan has pursued a policy of actively promoting generic medicines, setting specific volume-share targets with the aim of reducing patient burden and improving the efficiency of healthcare expenditure whilst maintaining quality of care.²⁰⁵ As of 2023, the volume share of generic medicines stands at 80.2 per cent, with 29 prefectures recording a share of 80 per cent or more (based on FY2022 data).²⁰⁶ The Fourth Period Basic Policy specifies that, whilst maintaining a stable supply of medicines as a fundamental principle, numerical targets are to be set at the prefectural level in line with new government objectives, and that necessary measures will be taken, including support for insurers in implementing differential notification and raising awareness of formularies²⁰⁷ among healthcare professionals.²⁰⁸

Effective and Efficient Utilization of Medical Resources

The appropriate use of finite medical resources contributes not only to the reduction of medical costs but also to the reduction of patient burden. For medical practices identified as being of limited effectiveness, such as the prescription of antibiotics for acute respiratory infections or acute diarrhea, efforts are under way to monitor current practices using nationally provided data, and to raise public and professional awareness.

Regional disparities in national healthcare expenditure and in the volume of medical resource inputs also present a challenge. According to FY2023 data, per capita national healthcare expenditure in Kochi Prefecture, the highest in Japan, is approximately 1.4 times that of Saitama Prefecture, the lowest.²⁰⁹ The government aims to halve regional disparities in age-adjusted per capita national healthcare expenditure. Measures employed include the Regional Medical Vision, the Medical Cost Optimization Plan, and the strengthening of incentives for health promotion, as discussed in Section

²⁰⁴ Ministry of Health, Labour and Welfare. "The Fourth Period Medical Cost Optimization Plan (FY2024–2029)." <https://www.mhlw.go.jp/content/12400000/001123575.pdf>

²⁰⁵ Ministry of Health, Labour and Welfare. "Annual Report on Health, Labour and Welfare, FY2023." <https://www.mhlw.go.jp/wp/hakusyo/kousei/22/dl/zentai.pdf>

²⁰⁶ Ministry of Health, Labour and Welfare. "Review of the Fourth Period Basic Policy on Medical Cost Optimization." <https://www.mhlw.go.jp/content/12401000/001309909.pdf>

²⁰⁷ A formulary refers to a prescribing guideline that standardizes the criteria for medicine selection within a hospital or region.

²⁰⁸ Ministry of Health, Labour and Welfare. "Summary: Fourth Period Basic Policy on Medical Cost Optimization." <https://www.mhlw.go.jp/content/12400000/001123575.pdf>

²⁰⁹ Ministry of Health, Labour and Welfare. "Analysis of Regional Disparities in Healthcare Expenditure (Electronic Claims Data), FY2023." https://www.mhlw.go.jp/content/iryohi_r05den.pdf

4 and this chapter. With regard to the volume of medical resource inputs, optimization is being pursued through support for physician recruitment using the Regional Medical and Long-Term Care Comprehensive Fund, construction and equipment of facilities, and clarification of role allocation between institutions.²¹⁰ In recent years, attention has also been drawn to refill prescriptions (rifiru shohozen), which can be used repeatedly up to three times by eligible patients with stable conditions. Expected simultaneously to shorten hospital waiting times and reduce patient financial burden, their wider dissemination is under consideration.²¹¹

Specific Health Check-ups and Specific Health Guidance

Specific Health Check-ups and Specific Health Guidance focus on visceral obesity, characterized by excessive accumulation of visceral fat, and metabolic syndrome, a condition in which multiple lifestyle-related disease risk factors (hypertension, hyperglycemia, and dyslipidemia) are present in combination. Specific Health Check-ups identify lifestyle-related disease risks at an early stage; Specific Health Guidance then helps individuals review lifestyle habits such as physical activity, diet, and smoking, with the aim of reducing visceral fat and thereby preventing and managing lifestyle-related diseases.²¹² The scheme targets individuals aged 40 to 74 enrolled in medical insurance; the uptake rate for FY2023 was 59.9 per cent. Whilst the overall rate has risen year on year, significant variation exists by insurer type: municipal National Health Insurance 38.2%; National Health Insurance Associations 51.9%; Japan Health Insurance Association 58.7%; Mariners' Health Insurance 52.8%; Health Insurance Societies 82.9%; Mutual Aid Associations 82.6%.²¹³ The new Medical Cost Optimization Plans envisage the introduction of outcome-based evaluation and use of ICT, with the expectation of further improvements in uptake rates and more effective implementation.²¹⁴

Healthcare Digital Transformation (Healthcare DX)

Healthcare digital transformation is indispensable for improving the efficiency and quality of services in the healthcare sector. Accelerating data collection, expanding its scope, and advancing the "visualization" of healthcare through digitalization and data sharing are also critically important in constructing a system capable of mounting a swift response to the next infectious disease crisis. In 2022, a Healthcare DX Promotion Headquarters was established, chaired by the Prime Minister, with a cross-ministerial remit organized around three pillars: the establishment of a national healthcare information platform, standardization of electronic medical record information, and fee schedule revision DX. To advance these initiatives, a "Healthcare DX Reiwa Vision 2030" Promotion Team, led

²¹⁰ Ministry of Health, Labour and Welfare. "Summary: Fourth Period Basic Policy on Medical Cost Optimization." <https://www.mhlw.go.jp/content/12400000/001123575.pdf>

²¹¹ Digital Agency. "Dashboard on Awareness and Usage of Refill Prescriptions." <https://www.digital.go.jp/resources/govdashboard/refill-prescription>

²¹² Government Public Relations Online. "What are Lifestyle-Related Diseases? Regular Check-ups for Prevention and Early Detection!" <https://www.gov-online.go.jp/useful/article/201402/1.html#secondSection>

²¹³ Ministry of Health, Labour and Welfare. "Implementation Status of Specific Health Check-ups and Specific Health Guidance, FY2023." <https://www.mhlw.go.jp/content/12400000/001492019.pdf>

²¹⁴ Ministry of Health, Labour and Welfare. "Summary: Fourth Period Basic Policy on Medical Cost Optimization." <https://www.mhlw.go.jp/content/12400000/001123575.pdf>

by the Minister of Health, Labour and Welfare, was established within the Ministry to examine and develop the specifics of implementation.²¹⁵

Data Health Plans

Japan, as a country with exceptional longevity, has since the early twenty-first century seen a policy trend emphasizing prevention and health promotion. Building on the achievement of electronic standardization of specific health check-up data and health guidance data, it has been required since 2015 that all insurers analyze claims and other data, and formulate and publish "Data Health Plans", business plans designed to maintain and promote the health of members based on such analysis. The purpose is to implement health management initiatives effectively and efficiently through a PDCA cycle, contributing both to member health and to employers' human capital management. More recently, efforts are being made to integrate Data Health Plans with other healthcare plans.²¹⁶

Health Management

Health management (kenko keiei) refers to the approach of considering employee health management from a managerial perspective and implementing it strategically. The continuously rising level of national healthcare expenditure has been identified as a factor adversely affecting the financial position of health insurance societies. As premiums increase, the burden on individuals and corporations rises. Furthermore, with the working-age population shrinking due to declining birth rates and population ageing, deterioration in employee health leads to declining corporate productivity and may adversely affect talent acquisition. For corporations, maintaining and improving employee health therefore represents not only a means of optimizing medical costs and enhancing productivity, but also an investment in the future.²¹⁷

Health management contributes to the enhancement of corporate image, organizational vitality, and business performance. The Ministry of Economy, Trade and Industry designates companies engaged in strategic health management as "Health Management Brand" companies, in principle selecting one company per industry sector, with the aim of ensuring that such companies are socially recognized and that health management is further promoted. In July 2017, the MHLW published the "Collaborative Health Guidelines for Promoting Data Health and Health Management," which set out procedures and case studies for implementing health management through "Collaborative Health" (Colabo Health), an approach in which employers and health insurance societies work in tandem to promote member health. It is envisaged that the promotion of Collaborative Health will allow Data Health and Health Management to function as mutually reinforcing and complementary elements.²¹⁸

²¹⁵ Ministry of Health, Labour and Welfare. "Annual Report on Health, Labour and Welfare, FY2023." <https://www.mhlw.go.jp/wp/hakusyo/kousei/22/dl/zentai.pdf>

²¹⁶ Ministry of Health, Labour and Welfare, Insurance Bureau; Health Insurance Bureau Federation. "Guidance on the Preparation of Data Health Plans." <https://www.mhlw.go.jp/content/12400000/001223896.pdf>

²¹⁷ Ministry of Economy, Trade and Industry. "Guidebook on Corporate Health Management (Revised 1st Edition)." http://www.meti.go.jp/policy/mono_info_service/healthcare/kenkokeiei-guidebook2804.pdf

²¹⁸ Ministry of Health, Labour and Welfare. "Collaborative Health Guidelines for Promoting Data Health and Health Management." <http://www.mhlw.go.jp/stf/houdou/0000170819.html>

Strengthening Incentives for Individuals and Insurers

One aspect of strengthening incentives for prevention and health promotion is the reinforcement of incentives directed at both individuals and insurers. With respect to individual incentives, insurers award healthcare points and provide insurance premium support in accordance with the preventive and health-promotion activities of their members. Examples include the granting of health goods or human health examination discount vouchers in recognition of completing specific health check-ups or improving health check-up results.²¹⁹

With regard to insurer incentives, revisions were made under the 2015 amendments to the National Health Insurance Act (coming into effect from FY2018) to enable each type of insurer to exercise its functions more readily. One measure was the creation of an Insurer Effort Support System for municipal National Health Insurance, along with a mechanism for evaluating initiatives, such as diabetes deterioration prevention on the basis of objective indicators and granting support funds accordingly. Another was a restructuring of the premium surcharge/reduction mechanism for Health Insurance Societies and Mutual Aid Associations, moving from evaluation based solely on specific health check-up implementation to a comprehensive framework incorporating multiple indicators including cancer screening and collaboration with employers. The mechanism took effect from FY2018, applying modest surcharges broadly across many insurers and graduated reductions in accordance with the level of attainment of designated indicators.

²¹⁹ Ministry of Health, Labour and Welfare. "On Insurer Incentives."
http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000163331.pdf

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