



Japanese Health Policy

Second edition

What is Japan Health Policy NOW?

Created in 2015 by Health and Global Policy Institute (HGPI), Japan Health Policy NOW (JHPN) is the only centralized platform in the world on Japanese health policy available in both Japanese and English.

As the world's attention turns to Japan, one of the world's fastest ageing countries, there is increasing interest in Japanese health policy and a growing need to share information on Japan's health policy with the world. JHPN is committed to addressing this need by delivering factual information about the Japanese health system, Japanese health policy stories of interest, recent Japanese health policy news, and a resource list for those who want to learn more about Japanese health policy.

For more information, please see
<http://japanhpn.org/en/jhpn/>

Introduction | Guidance for the Reader

Japan Health Policy Now is provided for a wide audience of stakeholders in the healthcare industry. It is intended to be a high level overview of the healthcare environment in Japan. It is updated about once every 2 years or so. For those of you reviewing, we have some suggestions on how you might approach the document to optimize your time.

For those who are in the healthcare industry but new to Japan or are generally interested in the healthcare environment in Japan, this document will serve as a well-rounded primer. It covers the policy environment, healthcare system, hospital, and product (e.g. medical device and pharma) sectors. It also introduces some key trends which will be moving the standard practices into the future. This last section is highlighted with comments and perspectives from various stakeholders in the system.

Executives in the Pharmaceutical or Medical Product Industries

JHPN can serve as a reference in many ways as it identifies key practices, statistics, and trends. For example, section 3 covers the healthcare provider system and section 5 provides an overview of medical products such as pharmaceuticals, medical devices, generics, and novel technologies. The document ends covering key trends into the future.

Public and Regulatory Officials

Japan is an important part of the global healthcare ecosystem. For global public and regulatory officials, there are some important sections covering key practices in the Japanese health insurance system. In addition, the final section of this document discusses key future trends and their impacts to Japan's healthcare system.

Academia

Academia is playing an increasingly important part of the overall healthcare environment around the world. And Japan is no exception. JHPN can serve as a resource for these key partners relative to the medical product industries and the healthcare provider system.

JHPN has a wide variety of information which can provide any reader with an overview of the healthcare system in Japan. We hope you find this useful as a key reference.

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1.1

Background | Japan's geography and demographics

Japan is an island nation in eastern Asia with an area of 377,887 square kilometers that is comprised of over 6,800 islands, including Honshu, Hokkaido, Kyushu, Shikoku, and Okinawa. Japan contains 47 self-governing administrative divisions referred to as prefectures.

The total population hovers around 127 million people, with about 90% living in urban areas. As of 2015, about 36.5% of the total population resided in Tokyo, Kanagawa Prefecture, Osaka, Aichi Prefecture, or Saitama Prefecture. Among these, the largest proportion was in Tokyo, which was home to 10.7% of the total population of Japan.¹

An ageing population with a declining birthrate^{2,3}

An ageing population coupled with a low birth rate are two major concerns facing Japan and its healthcare system.

Those aged 65 and over comprised 27.3% of the total population as of October 1, 2016. This figure is expected to approach 40% by 2060.

The old-age dependency ratio (the ratio of people aged 65 and over to people between the ages of 15 and 64) in 2015 was highest in Akita Prefecture (60.7) and Kochi Prefecture (59.2), and lowest in Okinawa Prefecture (31.2) and Tokyo (34.3).

The overall fertility rate in Japan was 1.45 in 2015. This rate was lowest in Tokyo (1.24) and highest in Okinawa (1.96).

Life expectancy and main causes of mortality

The people of Japan enjoy one of the highest life expectancies in the world, with the average being 91.35 years for females and 84.95 years for males.⁴ Mortality rates for the top nine causes of death in 2015 are listed in the following table (according to data from the Ministry of Health, Labour and Welfare (MHLW) and the Organisation for Economic Co-operation and Development (OECD)).

According to the World Health Organization (WHO), 79% of all deaths were related to non-communicable diseases (NCDs) in 2014. Amongst these, 30% of deaths were caused by cancers, 29%, by cardiovascular diseases, and 12%, by other NCDs.⁵

<Column> Ageing in Tokyo

Japan is not ageing across all regions at the same rate. Large metropolitan areas, such as Tokyo, Osaka, and Nagoya are at the forefront of aging in Japan.

According to Tai Takahashi*, between 2010 and 2025, the population of those aged 75 and over will grow by 7 million people, more than half of whom will reside in the Greater Tokyo Area (Tokyo, Kanagawa, Chiba, and Saitama), Osaka, and Nagoya. These three regions, however, comprise a mere 2% of Japan's total land area, underscoring the urban nature of Japan's "super-ageing society." Takahashi also points out that Tokyo faces serious additional challenges regarding the number of care facility beds, which is equal to just half the national average. This shortage may become increasingly serious as the population continues to age.

*Reference: "Regional Differences in the Peak of Healthcare Demand and the Level of Medical-Social Resources: Rebuilding a Medical-Social Service Delivery Structure," Presentation by Professor Tai Takahashi of the International University of Health and Welfare at the 9th Meeting of the Committee on National Social Security Reform, 2013.

¹ Statistics Bureau, Ministry of Internal Affairs and Communications (14 April 2017). Demographic forecast. (accessed 15 September 2017) Retrieved from: <http://www.stat.go.jp/data/jinsui/2016np/index.htm#a05k28-b>

² Cabinet Office (2017). White paper on ageing society. (accessed 24 July 2017) Retrieved from: http://www8.cao.go.jp/kourei/whitepaper/w-2017/zenbun/29pdf_index.html

³ Director General for Policy Planning and Evaluation, Ministry of Health Labour and Welfare (2017). Vital statistics in Japan. (accessed 24 July 2017) Retrieved from: <http://www.mhlw.go.jp/toukei/list/dl/81-1a2.pdf>

⁴ Cabinet Office (2017). White paper on ageing society. (accessed 24 July 2017) Retrieved from: http://www8.cao.go.jp/kourei/whitepaper/w-2017/zenbun/29pdf_index.html

⁵ World Health Organization (2014). Noncommunicable diseases country profiles 2014: Japan. (accessed 24 July 2017) Retrieved from: http://www.who.int/nmh/countries/jpn_en.pdf?ua=1

| Cause of death | Mortality rate (per 100,000) ⁶ | OECD average mortality rate (per 100,000) ^{7*} |
|-------------------------|--|--|
| Cancer | 290.3 | 211 |
| Heart disease | 156.5 | 122 |
| Pneumonia | 97.8 | n/a |
| Cerebrovascular disease | 94.1 | 69 |
| Senility | 55.5 | n/a |
| Accident | 31.5 | n/a |
| Suicide | 20.7 | 12.4 in 2011 |
| Liver disease | 12.7 | n/a |
| Tuberculosis | 1.7 | n/a |

*Where available

Ranked by the burden that each disease places on the lives of sufferers as measured in DALYs (Disability-Adjusted Life Years)*, the most critical diseases within the Japanese population are cancers, cardiovascular diseases, diabetes, neuro-psychiatric diseases, musculoskeletal diseases, respiratory diseases, other NCDs, external injuries, and infectious diseases.⁸ It is expected that the burden of life-style related diseases and degenerative diseases will increase alongside demographic changes such as ageing.

The World Bank estimated in 2015 that the under 5 mortality rate (U5MR) for Japan stood at 3 per 1,000 live births and the maternal mortality ratio was 6 per 100,000 live births. These figures reflect a decrease of nearly 50% when compared to data from 1990.⁹

*DALYs are an indicator of disease burden which assesses the amount of harm caused to health by specific diseases and injuries. DALYs are calculated by adding the total of years of life lost (YLL) due to premature death and the years of life lived with disability (YLD).

<Column> A population on track to decline, with low expectations for growth even among the population aged 65 and over

Between 2010 and 2040, the population aged 65 and over will increase by 9 million. Over the same time period, the population under age 65 will decrease by 30 million. Starting sometime around the year 2040, it is expected that growth in the older population will plateau, while the working population will sharply decrease, causing the overall population to shrink by around 15%. This will increase the proportion of people aged 65 and over in Japanese society.

⁶ Ministry of Health Labour and Welfare (2017). Vital statistics in Japan. (accessed 2 February 2018) Retrieved from: <http://www.mhlw.go.jp/toukei/list/dl/81-1a2.pdf>

⁷ OECD (2015). Health at a Glance 2015: OECD Indicators. Paris: OECD Publishing, 2015.

⁸ World Health Organization (2015). Japan: WHO statistical profile. (accessed 24 July 2017) Retrieved from: <http://who.int/gho/countries/jpn.pdf?ua=1>

⁹ The World Bank (2015). Mortality rate, under-5 (per 1,000 live births). (accessed 24 July 2017) Retrieved from <http://data.worldbank.org/indicator/SH.DYN.MORT>

1.2

Background | The history of public healthcare insurance

The current Japanese healthcare system can be best understood by reviewing its origins. The public health insurance program in Japan is a combination of three separately developed structures—the employment-based health insurance system, the residence-based National Health Insurance system, and the medical insurance system for those aged 75 and over. Today, these three structures combined form the basis of one of the largest healthcare insurance programs in the world, covering nearly all Japanese citizens and long-term residents, over 127 million people. In light of historical circumstances and following numerous revisions to the Health Insurance Act since its introduction in 1922, these insurance systems are administered by a variety of insurers.

The history of the public health insurance program in Japan

The beginnings of Japan's system of public health insurance system

After sweeping through England from the second half of the 18th century and throughout the 19th century, the industrial revolution finally reached Japan. Japan's industrial revolution began in earnest when state-owned enterprises were privatized in the second half of the 19th century. Just like the rest of the world, this caused a sharp increase in the number of Japanese laborers working in environments such as coal mines and factories. As a result, issues surrounding the improvement of working conditions and the protection of workers' rights became urgent due to labor movements and social movements. This led to the enactment of the Factory Act in 1916, which regulated employment and compelled factory owners to provide support to workers in the event of workplace injury or fatality.

However, labor movements started by labor unions were based on socialism, and resistance to socialism remained a major hurdle for the Japanese government. The government did not view the labor movement as entirely dangerous. It distinguished between moderate reform and radical reform and worked to prevent confrontations between social classes by permitting moderate labor movements using a Bismarck-style “Carrot and stick” approach. The “stick” in this approach refers to actions that suppressed labor movements. The first “carrot” appeared in 1922, when the Health Insurance Act came into effect. The main purpose of this act was to provide compensation to workers or their families in the event that a worker had a workplace accident or fell ill while not on the job. The concept of the Health Insurance Act itself dates back to the 1890s, when Minister of Home Affairs Shinpei Goto started discussions within the government after recently returning to Japan from a study trip to Germany. However, the topic did not become a priority issue for the government, so many years of effort were required before it was finally enacted. Also, at the time, health insurance for laborers was considered more strongly an industrial policy rather than a medical policy, so it was under the jurisdiction of the same ministry as the Factory Act, the Ministry of Agriculture and Commerce.

Meanwhile, the Great Depression began in the United States in 1929. Shockwaves were sent through Japan's farming communities when export prices for agricultural products to the U.S. fell one after another, starting with exports of raw silk thread. An additional blow fell when a bumper crop in 1930 sent the price of rice plummeting, further compounding the economic problems already facing Japan's farming communities. Entering the 1930s, farming communities became an important source of manpower for the Japanese military, so the health and nutritional status of their people became an issue of military strength. The Ministry of Home Affairs began to consider establishing an insurance system for the general populace starting with those in farming villages that would provide wide coverage for people who were not employees. It is said this decision was based upon the fact

that the long-established “Jorei” system for providing community healthcare similar to medical aid associations already existed in every region of Japan, particularly in farming communities. The decision was also influenced by the fact that the Health Insurance System that had been created for employees was already starting to show results. It is also said that the Japanese government made this decision after seeing the results of similar systems in Sweden and Denmark.

The former National Health Insurance Act was submitted to the Diet in 1937, but ended up classified as unresolved and rejected after the dissolution of the House of Representatives. When the Ministry of Health and Welfare (now the Ministry of Health, Labour and Welfare) was formed the following January, in 1938, income restrictions that had been an insurance prerequisite were abolished, and insurance became available to non-employees. The condition that insurance be employment-based was also abolished for both the insured and those not covered by employee insurance. This system was replaced by a system in which insurance was provided through location-based insurance associations that viewed municipalities as independent units. This formed the basis of the current system of residence-based National Health Insurance that was enacted in March 1938.

The successful establishment of universal health coverage(UHC)

After World War II ended in 1945, the Supreme Commander for the Allied Powers (SCAP) issued the "Three principles of public assistance" for Japan, making the government responsible for ensuring equality and minimum standards of living. This meant the government had to be more proactive in maintaining the health of the people. In 1948, the previous National Health Insurance system was revised, making it a rule that the insured were under the jurisdiction of local governments rather than regional associations. However, given the economic situation after the war, there were still problems that prevented National Health Insurance from becoming widespread. Even by 1956, one-third of the population of Japan was still unenrolled in any form of health insurance. Due to this, the then Prime Minister Ichiro Hatoyama declared the establishment of "Comprehensive health insurance that covers all citizens" in his annual speech on policy guidelines. This was a massive step forward in the effort to insure everyone. The current National Health Insurance Law was enacted in 1958. It made regional governments legally responsible for the administration of insurance associations and compelled all citizens to enroll in the public insurance scheme if they were not already covered by employee's insurance or a Mutual Aid Association (MAA). That same year, a new Public Health Insurance act was enacted. After a grace period of 3 years, public health insurance unions were established in all municipalities, allowing Japan to successfully achieve a world-class system of universal healthcare in 1961.^{10,11,12}

Coverage for the older population

In 1973, Japan forged a unique health insurance structure for its older population, reallocating public funds to subsidize the 30% of costs typically covered by patients within the NHI cost-sharing scheme and effectively making healthcare free for people aged 70 and over.¹³ Japan simultaneously introduced a high-cost medical care benefit system which at first covered only family members of employees via the employment-based health insurance, not extending to employees themselves. Later, employees along with their families came

<Column> Free healthcare for people aged 70 and over: The “biggest mistake” in the history of health policy in Japan

Free healthcare for the elderly is now considered by the Government of Japan to be the “biggest mistake in the history of health policy in Japan” (according to a former MHLW official). While drastically improving access to healthcare among the older population, the system resulted in over-provision of care and medical products, including pharmaceuticals. Older patients flooded hospital waiting rooms to the extent that they essentially became centers of social activity for some people. During that era, it was not uncommon to hear two older people in a waiting room joke, “Ms. Yamada isn’t here today. She must not be feeling well!” The moral hazards created by free healthcare were so extreme that the government moved to revise the policy for people aged 70 and over, re-requiring cost-sharing. However, this proved tremendously

¹⁰ Kitayama, T. (2011). Explaining the Institutional Change of Health Politics in Japan: Localities Nationalized?. Yukikaku Publishing Co., Ltd.

¹¹ Sakaguchi, T. (1977). The History of Japan’s Social Insurance Systems. Keiso Shobo

¹² Yoshihara, K., & Wada, M. (2008). The History of Japan’s Health Insurance Systems. Toyo Keizai Inc.

¹³ Ministry of Health, Labour and Welfare (2016). The status of medical care for the elderly. (accessed 29 January 2018) Retrieved from http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000125580.pdf

to enjoy the benefits of this system via National Health Insurance, when employment-based health insurance finally grew to also cover employees. Between 1973 and 1980, healthcare spending for people aged 70 and over increased more than fourfold, leading to sustainability concerns and the eventual passage of the 1982 Public Aid for the Aged Act. This act, implemented in 1983, put an end to free healthcare for the elderly by requiring that they pay small copayments.¹⁴ In addition, this legislation helped to subsidize the NHI program by transferring revenue from employment-based health insurance to NHI. As a result, the Public Aid for the Aged Act is considered one of the most critical pieces of healthcare legislation in the history of Japanese health policy.

The Health Services Scheme for the Aged and the medical care system for the retired

The Public Aid for the Aged Act of 1982 created the basis for the Health Services Scheme for the Aged. This scheme, which was administered by municipalities, covers people aged 75 and over as well as those bedridden aged 65 and over (People aged 70 or over born prior to September 30, 1932, were covered by the Health Services Scheme for the Aged). Funding for the scheme was provided by contributions from medical insurers, public funds, and partial contributions by the insured. This scheme was in place for nearly 25 years, only being revised in 2008. There were many reasons for the revision. Chief among them was the lack of transparency regarding distribution of medical expense burden between the young and the old. Through the scheme, a part of every premium contributed by the members of any health insurance plan was transferred to municipal governments. In other words, the groups collecting premiums (insurance schemes) were not the same as the groups paying contributions (municipalities), making it difficult to know how contributions were actually spent. This scheme was finally discontinued in April 2008 alongside the creation of the Medical Insurance System for the Latter-Stage Elderly targeting people aged 75 and over.¹⁵ The cost-sharing details between the young and the old are much more transparent in this system. Furthermore, this system established governmental unions in prefectural associations across the country to act as central locations for the collection and payment of insurance premiums. This system also has clearly defined regulations regarding the responsibilities of management and the use of public finances. In addition to the previously mentioned systems, in 1984, the Government created the Retired Persons Healthcare System to relieve the building pressure on public finances brought on by increasing numbers of retirees leaving employment-based insurance schemes and coming under the coverage of NHI. The Retired Persons Healthcare System covered people aged 65 and under who were enrolled in NHI, people on employee pensions for over twenty years, and people who elected to receive retirement pensions after the age of forty and had done so for 10 years or more. Dependents were also covered by this system if they satisfied a fixed set of accreditation criteria. This system was administered by municipal governments, and funding was sourced from premiums contributed by system members, as well as premiums paid to employment-based health insurance plans. The Retired Persons Healthcare System itself was discontinued following the establishment of the Medical Insurance System for the Latter-Stage Elderly in April 2008¹⁶.

A new medical insurance system framework for the older population

The 2006 reform of the Japanese medical system is tremendously important when trying to understand health policy in Japan. This reform created a new healthcare system for people aged 75 and over. A number of reasons led to the creation of this new system. The first was related to Japan's residence-based insurance, a part of NHI that covers people residing in Japan who are not enrolled in employment-based health insurance plans. The health insurance system was set up such that when people retired who had formerly been enrolled in employment-based health insurance plans, they would then be enrolled in Community Health Care Plans.¹⁷ Since people generally

¹⁴ Ikegami Naoki (2014). Universal Health Coverage for Comprehensive and Sustainable Development – Synthesis of research in 11 countries. Japan Center for International Exchange. (accessed 29 January 2018) Retrieved from <http://www.icie.or.jp/japan/pub/publst/1453/1453all.pdf>

¹⁵ Ministry of Health, Labour and Welfare. Changes to the healthcare system for the elderly. (accessed 22 August 2017) Retrieved from <http://www.mhlw.go.jp/bunya/shakaihoshou/iryouseido01/info02d-25.html>

¹⁶ Ministry of Health, Labour and Welfare. Amendments to the medical insurance system. (accessed 22 August 2017) Retrieved from <http://www.mhlw.go.jp/bunya/shakaihoshou/iryouseido01/taikou05.html>

¹⁷ Ministry of Health, Labour and Welfare. The medical insurance system of Japan. (accessed 22 August 2017) Retrieved from <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000172084.pdf>

retire at older ages, the average age of the population enrolled in NHI (via these plans) grew older and older as time passed. This shift placed enormous financial pressure on the NHI since older people tend to incur greater medical expenses. The 2006 reform aimed to respond to this structural challenge by establishing a framework that allowed people aged 75 and over to be supported by society as a whole. Specifically, a new system was set up requiring people aged 75 and over to cover 10% of their medical expenses, while the remaining 90% is covered by the working population and public funds. A framework was also created by insurers to adjust costs for people aged 65 to 74 by having them enroll in either Community Health Care Plans or employment-based health insurance. The framework for those aged 75 and over came to be known as the Medical Insurance System for the Latter-Stage Elderly, while the framework for those aged 65 to 74 supports people considered to be “Early-stage” elderly.

The Long-Term Care Insurance System

Prior to the establishment of the Long-Term Care Insurance System, welfare and medical care for the elderly were delivered via separate systems. In terms of welfare, municipal governments selected the types of services people were eligible for as well as the institutions from which they could receive the services. Service recipients had no say in these matters. Service fees were decided according to the incomes of recipients and the incomes of their dependents, leading to heavy burdens for middle-class households. As for medical care for people aged 75 and over, a lack of infrastructure for welfare services limited society’s ability to provide long-term care to people in need of services, including daily care in hospitals and care related to specific medical treatments which required longer periods of hospitalization.¹⁸

As the Japanese population has aged, the focus of the healthcare field has shifted from acute illnesses toward the provision of integrated and continuous medical and nursing care for those with chronic conditions. Fewer and fewer families are now living with their elderly relatives compared to in the past, and the average age of family members providing care to elderly relatives is increasing. The combined effect was an increase in the number of people with no option for medical care but a long-term hospital stay, which put a strain on public finances. The Long-Term Care Insurance Act of 1997 was created to address this issue. This act established the Long-Term Care Insurance System, which covers all people aged 65 and over, as well as people aged 40 and over who are in need of long-term care. This system gives users the freedom to select the type of services they need, as well as their service providers. This act also created the position of “Care Managers” who are able to assist users in selecting care providers.¹⁹ Users are charged 10% of the medical fees for the services they select, irrespective of their income (although above a certain level of income, they are charged 20%). The system differs from NHI by mandating a “maximum amount of financial support.” After a certain level of support, users must cover the costs of all excess services.

Other healthcare legislation

Implemented in 1948, the seminal Medical Care Act defined criteria for the basic medical services to be provided by public hospitals.²⁰ The Medical Care Act has since undergone eight revisions in order to better align the provision of medical facilities with community needs as well as to introduce the system of Medical Care Plans.

A more recent piece of major health policy legislation is the Health Care System Reform Act of 2015, which changed the shape of the healthcare insurance system. This act, which will go into effect in 2018, moves oversight of the residence-based NHI from the municipal level to the prefectural level. To support the transition, this act provides prefectures with increased authority and responsibility related to financing and healthcare delivery

¹⁸ Ministry of Health, Labour and Welfare (2015). The current state of the public nursing-care insurance system and its future role. (access 22 August 2017) Retrieved from http://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/201602kaigohokenntoha_2.pdf

¹⁹ Ikegami Naoki (2017). Medical care in Japan; Its history and organization – Direction of future reforms. Nikkei Book Publishing Company.

²⁰ Ministry of Health, Labour and Welfare (2007). 2007 White Paper of the Ministry of Health, Labour, and Welfare. (accessed 29 January 2018) Retrieved from <http://www.mhlw.go.jp/wp/hakusyo/kousei/07/dl/0101.pdf>

systems. As one MHLW official put it, it is “the biggest change to healthcare in Japan since the establishment of the modern healthcare system.”

1.3

Overview of major legislation

| Year | Policy | Details |
|------|--|--|
| 1922 | Establishment of the Health Insurance Act | <ul style="list-style-type: none"> • Provided health insurance to employees with a certain level of income |
| 1938 | Establishment of the National Health Insurance Act | <ul style="list-style-type: none"> • Established National Health Insurance (NHI), a residence-based insurance program for farmers, the self-employed, the retired, and the non-employed, administered by municipal governments on a voluntary basis |
| | Establishment of the Ministry of Health and Welfare | |
| 1939 | Establishment of Health Insurance for Employees Act | <ul style="list-style-type: none"> • Provided health insurance to employees working at financial companies etc. |
| 1942 | Health Insurance Act amended | <ul style="list-style-type: none"> • Integrated the Health Insurance Act and Health Insurance For Employees Act • Introduced a system of partial cost-sharing |
| 1948 | Establishment of the Medical Care Act | <ul style="list-style-type: none"> • Legislated the establishment and management of hospitals, clinics, and other facilities, as well as their scope and number of personnel |
| 1958 | National Health Insurance Act amended | <ul style="list-style-type: none"> • Mandated that all municipalities establish and administer residence-based NHI programs • NHI became compulsory for those not covered by other plans |
| 1961 | Universal Healthcare achieved | <ul style="list-style-type: none"> • Landmark achievement in Japanese health policy history made possible through the expansion of NHI after all municipalities were mandated to administer a NHI program in 1959 • Out-of-pocket responsibility becomes 0% for insured people with employee insurance, 50% for dependents, and 30% for those enrolled in NHI • Establishment of high-cost medical expense system |
| 1963 | Establishment of the Act on Social Welfare for the Elderly | <ul style="list-style-type: none"> • Establishment of special elderly care homes • Legislation related to home help |
| 1972 | Act on Social Welfare for the Elderly amended | <ul style="list-style-type: none"> • Created a new structure for those 70 and over and made care free for nearly all people age 70 and over • Reduced copayments within NHI for other enrollees |
| 1973 | Health Insurance Act amended | <ul style="list-style-type: none"> • Establishment of medical expenses for the elderly payment system • Fixed rate of state aid for Government-Managed Health Insurance |
| 1982 | Public Aid for the Aged Act | <ul style="list-style-type: none"> • Retracted free care for those aged 70 and over by imposing a small co-payment |

| | | |
|------|---|--|
| | | <ul style="list-style-type: none"> • Stipulated coverage of medical expenses for the elderly via fiscal adjustment among insurers. Treated people aged 70 and over separately from the existing health insurance system, subsidizing costs via public funding (national government 2/3, prefectural governments 1/6, municipal governments 1/6) and contributions from insurers in the existing health insurance system. |
| 1985 | The first revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Introduced regional medical planning for the management of hospital beds |
| 1990 | “Eight Acts” ²¹ related to welfare amended | <ul style="list-style-type: none"> • Municipalities were obligated to formulate municipal healthcare plans for the elderly |
| 1993 | The second revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Specified “advanced care hospitals” and created a new structure for “health facilities for long-term recuperation” |
| 1997 | Establishment of the Long-Term Care Insurance Act | <ul style="list-style-type: none"> • Launched a mandatory social insurance program that covers care for older people with health issues, partially relieves caregiver burdens, and addresses the needs of the aging population |
| | The third revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Launched the regional medical care support hospital system • Set general regulations for informed consent |
| 2000 | Partial revision of the Health Insurance Act | <ul style="list-style-type: none"> • High-cost medical expense system amended • Revised the upper limit for health insurance premium rates • Abolished out-of-pocket expenditures on medicine related to the elderly • Revised a portion of expenditures related to the elderly |
| | The fourth revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Introduced a bed classification system that required hospitals to report hospital bed use under the categories of “general” or “treatment” • Implemented 2-year mandatory clinical training period for doctor licensing • Made medical safety management systems legally mandatory for all medical facilities |
| 2002 | Partial revision of the Health Insurance Act | <ul style="list-style-type: none"> • Revised out-of-pocket expenditures • Introduced total compensation system for health insurance premiums • Increased insurance premium rate for Government-Managed Health Insurance • Revised calculation method for medical expense contributions for the elderly • Other measures, including those to strengthening the financial foundation of NHI |

²¹ Eight welfare-related acts: (1) Act on Social Welfare for the Elderly, (2) Act on Welfare for Physically Disabled Persons, (3) Act on Welfare for Mentally Retarded Persons, (4) Child Welfare Act, (5) Act on Welfare for Mothers with Dependents and for Widows, (6) Social Welfare Act, (7) Aid for the Aged Act, and (8) Social Welfare and Medical Business Corporation Act

| | | |
|------|---|--|
| 2005 | Long-Term Care Insurance Act amended | <ul style="list-style-type: none"> • Established preventive benefit and regional support projects for the creation of a preventative medicine system • Following a review of facility benefits, it become no longer possible to use benefits for expenses relate to food and housing at long-term care facilities. A supplementary benefits program for low income users is set up • Created of community-based services to establish new service systems, enhance residential services, improve the integrated community care system, strengthen support for middle-income households, and coordinate medical care and nursing care / establish a clearer division of roles • Established insurance fees for primary beneficiaries that reflected, in detail, the ability of that person to pay expenses, following a review of the state of medical expenditures and the management system for such expenditures. Also revised the long-term care licensing system, strengthened insurer functions, and revised cost-sharing schemes and other issues. |
| 2006 | Health Care Reform Act | <ul style="list-style-type: none"> • Established a new medical care service system targeted at people aged 75 and over • Establish a public corporation to hand over the administration of Government-Managed Health Insurance for employees of SMEs from the national Government to the prefectural governments |
| | Partial revision of the Health Insurance Act | <ul style="list-style-type: none"> • Formulated a medical cost optimization plan to optimize medical expenses over the medium- to long-term, such as lifestyle disease measures and the correction of long-term hospitalization fees • Revised the content and scope of insurance benefits • Abolished medical facilities that only provided long-term care • Established a new medical care service system for the elderly |
| | The fifth revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Promoted public information about healthcare facilities at the prefecture level |
| 2008 | Long-Term Care Insurance Act and Act on Social Welfare for the Elderly amended | <ul style="list-style-type: none"> • Created a business management system under laws and regulations for nursing care service providers • Issued advance notification on the suspension or abolition of nursing care service providers • Made the clarification of services at the time of a nursing care service provider suspension or abolition mandatory. |
| 2008 | Cabinet Order to revise part of enforcement ordinance for the Health Insurance Act etc. | <ul style="list-style-type: none"> • Revised the calculation criteria for high-cost medical expenses • Established requirements for payment related to high cost long-term care and calculation standards related to nursing care |
| | Summary Report of the National Conference on Social Security | <ul style="list-style-type: none"> • Established the introduction of a hospital bed function reporting system and a vision for community care • Called for the strengthening of the roles of prefectures and transitioning of NHI management to prefectures |

| | | |
|------|---|---|
| | | <ul style="list-style-type: none"> • Revised the medical corporation system and social welfare corporation system • Called for collaboration between medical care and nursing care and construction of an integrated community care system • Called for Financial support to promote the reform of the provision of medical and nursing care services • Called for a studies on training general practitioners, communicating information to the public, the duties of medical professionals, and the establishment of team medical care. Emphasized that data should be continuously collected and periodically reevaluated. • Called for the stabilization of the health insurance system, ensuring fairness in cost-sharing related to insurance premiums • Called for prioritization and efficiency improvements related to medical benefits (a correction of the range of eligible medical treatment etc.) |
| 2009 | Cabinet Order to revise part of enforcement ordinance for the Health Insurance Act | <ul style="list-style-type: none"> • Revised the Childbirth Lump-Sum Allowance and benefit for the childbirth of a family member (increase of 40,000 yen) |
| 2011 | Establishment of the Act Revising a Portion of the Long-Term Care Insurance Act to Strengthen the Foundation of Long-Term Care Services | <ul style="list-style-type: none"> • Strengthened collaborations between medical and nursing care providers. Promoted comprehensive support (integrated community care system) for caregivers etc. who cooperate with medical care, nursing care, prevention, housing, and living support services. • Established Long-Term Care Service Plans based on an understanding of the regional needs and issues in the places where people live, created a 24-hour regular and periodic care services and complex services • Extended the date for the elimination of hospital beds used only for long-term care • Promoted the supply of housing with in-home care services for the elderly |
| 2012 | National Health Insurance Act amended | <ul style="list-style-type: none"> • Transferred the financial administration of NHI programs from the municipal level to the prefectural level to strengthen the financial basis of NHI |
| 2013 | Partial revision of the Health Insurance Act and other acts | <ul style="list-style-type: none"> • Took measures including the two-year extension of fiscal support for the Japan Health Insurance Association which was previously in place from 2010 to 2012 (These include: 1. government subsidies, and 2. methods by which insurers could handle money owed to support healthcare for those age 75 and over) • Raised the share of healthcare expenditures incurred by the Japan Health Insurance Association that were covered by Government subsidies from 13% to 16.4% for two years |

| | | |
|------|---|--|
| | Establishment of social security reform program | <ul style="list-style-type: none"> • Clarified items to be examined for a reform of the healthcare system and the long-term care insurance system • Established a system for the reporting of hospital bed functions • Considered all aspects of the total compensation ratios for supporting people aged 75 and over • Revised out-of-pocket expenditures among people aged 70 to 74 years old • Revised the high-cost medical expenditure system |
| 2014 | Establishment of the Law to the Related Acts for Securing Comprehensive Medical and Long-Term Care in the Community | <ul style="list-style-type: none"> • Set up new funds within prefectures that utilize consumption tax revenue to promote strong collaboration between medical care and nursing care • Created the requirement that medical institutions report the functions of hospital beds (beds for intensive , acute, recovery, or chronic patients) to prefectural governors in order to ensure the efficient and effective provision of healthcare in each community. Also created the requirement that prefectures formulate a regional medical vision for their local healthcare systems based on that. • Enhanced community support projects and shifted funds for preventative medicine benefits to community support projects in order to foster a comprehensive regional care system and ensure fair cost-sharing. |
| 2014 | Cabinet Order to revise part of enforcement ordinance for the Health Insurance Act | <ul style="list-style-type: none"> • Revised the Childbirth Lump-Sum Allowance. • Revised criteria for calculating high-cost medical care benefits and combined medical treatment costs for high-cost long-term care |
| | The sixth revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Promoted integrate care and the analysis of hospital bed information through the creation of the Bed Classification System and Integrated Community-based Care Plan • Introduced measures to address physician and nurse shortages • Introduced a classification renewal system for hospitals recognized as “advanced treatment hospitals” • Introduced measures to improve the work environment for healthcare workers • Promoted home healthcare • Promoted the improvement of the clinical trial system • Introduced a system to investigate medical accidents • Revised the healthcare corporations system |
| | Establishment of Act for Securing Comprehensive Medical and Long-Term Care | <ul style="list-style-type: none"> • Implemented measures aimed at ensuring the efficient and effective provision of medical care at the community level • Established the integrated community care system and revised cost-sharing to be more fair. |

| | | |
|------|--|---|
| 2015 | Establishment of the Act Revising a Portion of the National Health Insurance Act to Build a Sustainable Health Insurance System | <ul style="list-style-type: none"> • Transferred responsibility for the fiscal management of NHI from municipal governments to prefectural governments • Increased insurance premiums for employees of large corporations and civil servants • Established "patient offer system" that allows users to cover medical expenses through a combination of insurance benefits and out-of-pocket funding. |
| | The seventh revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Established a system for the creation of corporations to promote regional medical collaborations • Revised the medical corporation system |
| 2017 | The eighth revision to the 1948 Medical Care Act | <ul style="list-style-type: none"> • Established regulations on governance reforms at advanced treatment hospitals • Established restrictions on what medical institution websites, publications, and so on, can say (restrictions on false or exaggerated claims). |
| 2017 | Cabinet Order to revise part of enforcement ordinance for the Health Insurance Act | <ul style="list-style-type: none"> • Revised calculation criteria for high-cost medical expenditures among insured people over 70 years old |
| | Establishment of the Act Revising a Portion of the Long-Term Care Insurance Act to Strengthen the Integrated Community Care System | <ul style="list-style-type: none"> • Created a system to make it possible for municipal governments to make use of insurer functions and work toward helping patients live independently and toward preventing sick patients from growing worse. • Established a new kind of nursing-care insurance facility that combines functions such as daily medical management and end-of-life care and terminal care with living facilities. • Set out requirements for people using Long-Term Care Insurance with high-cost medical expenditures who were previously asked to cover 20% of their expenses to now cover 30%. |
| 2018 | Prefectural Unitization of NHI | <ul style="list-style-type: none"> • Transferred responsibility for fiscal management of NHI from municipal governments to prefectural governments. |

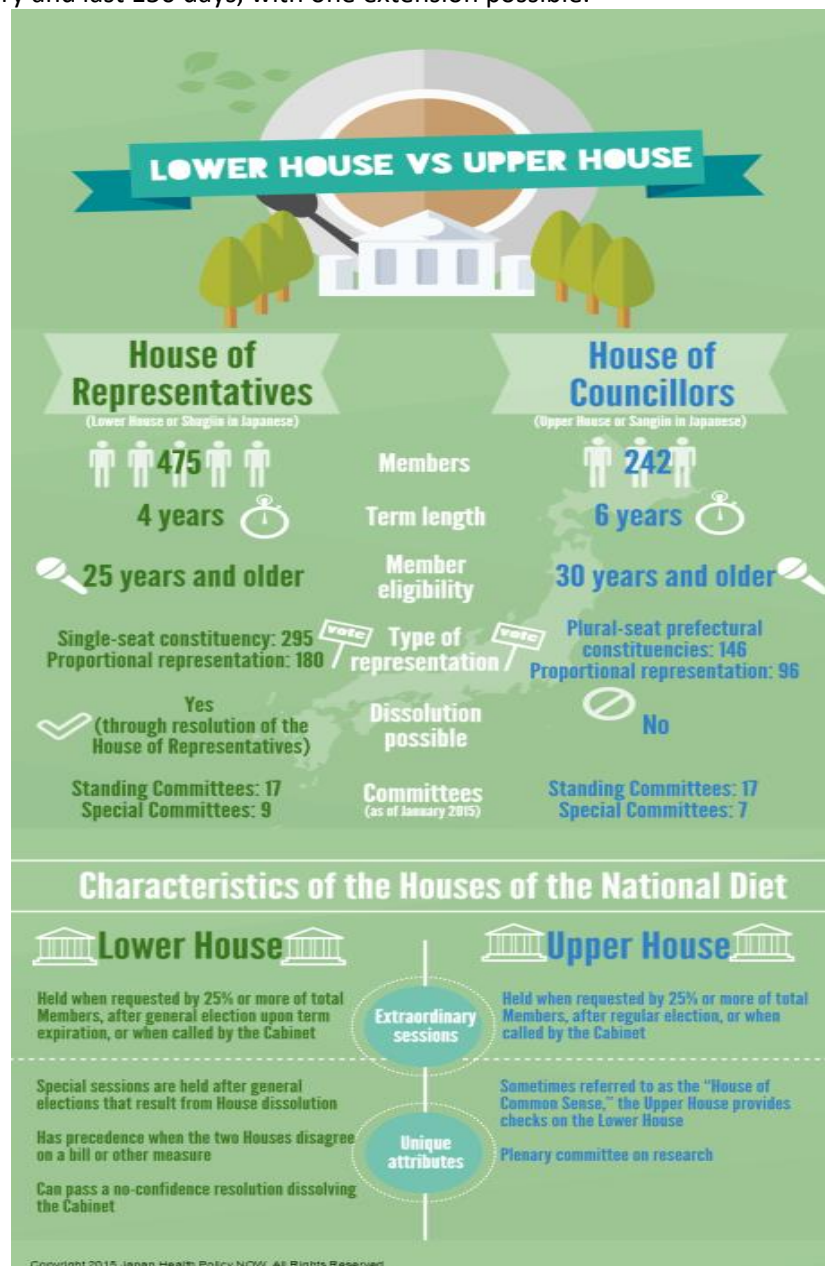
2.1

Processes and players | Japan's government

The Constitution of Japan, created in 1946 and implemented in 1947, laid the foundation for Japan's parliamentary system of government. This system is divided into three branches: the legislative branch, the executive branch, and the judicial branch. Power is separate and checks and balances exist between the three branches.

The legislative branch

The legislative branch is comprised of the country's sole law-making body, the National Diet. The Diet has two Houses, the House of Representatives and the House of Councillors, both comprised of members elected by the public. Members of each House are required to serve on at least one standing committee during ordinary sessions, which begin in January and last 150 days, with one extension possible.



The executive branch

The executive branch is comprised of the Cabinet Office, endowed with administrative authority, and led by the Prime Minister. The House of Representatives nominates the Prime Minister, who is then officially appointed by the Emperor and designates the ministers of state who comprise the Cabinet. The constitution stipulates that the majority of ministers of state be selected from the Diet.²² The Cabinet Secretariat provides support to the Cabinet and the Prime Minister.

State Ministers remain in office until they are dismissed by the Prime Minister or the Lower House passes a no-confidence resolution (or rejects a confidence resolution). Within 10 days of the passing of a no-confidence resolution (or a rejection of a confidence resolution) either the House of Representatives is dissolved or the members of the Cabinet collectively resign. The Cabinet includes the Cabinet Office, Cabinet Agencies, and 11 Ministries, including the Ministry of Health, Labour and Welfare, and the Ministry of Finance. These central government offices carry out various policies and draft cabinet bills.²³

The judicial branch

The judicial branch is comprised of the Supreme Court and four types of lower courts. The Supreme Court is endowed with the power of judicial review and ensures that legislation and actions taken by the Cabinet and the Diet are constitutional. The Supreme Court's chief justice is appointed by Cabinet nomination and official appointment by the Emperor. The other 14 justices are appointed by the Cabinet. Justice appointments to the Supreme Court are periodically reviewed in intervals of 10 years, starting with the first general election of House of Representatives following their appointment until the judge reaches the mandatory retirement age of 70. Appointments may be terminated through a majority vote, although this has yet to happen. Below the Supreme Court are high courts, district courts, family courts, and summary courts. Most trials involve one to three judges. In 2009, criminal trials began to include the general public through the use of lay judges.²⁴

<Column> Frequent national elections

Japan has frequent national elections. Including Parliamentary (Diet) elections, there were 7 elections between 2005 and 2015 – that's one election every 1.5 years. Lower House elections are held so frequently (once every 2.5 years over the past 10 years) that it is not uncommon for Members of the Lower House to leave office without completing a full four-year term. In addition, every three years, an election is held for half of the Upper House. This election has significant impact as it serves as a mid-term evaluation of the administration. Add to this the local elections held nation-wide every four years, and the municipal elections which, in a real sense, are actual contests between the ruling and opposition parties, and the number of elections further increases. As a result, the government, the ruling party, and each political party must pay critical attention to elections, which leads to a certain level of instability in politics and, what some consider, an easy avenue for the influential voices of older persons to affect policy (for this reason, Japan is sometimes called a "Silver Democracy").

²² Ministry of Internal Affairs and Communications. Types of Elections. (Accessed 30 January 2018) Retrieved from http://www.soumu.go.jp/senkyo/senkyo_s/naruhodo/naruhodo03.html#chapter1

²³ Cabinet Office. Pamphlet on the organization and functions of the Cabinet. (Accessed 30 January 2018) Retrieved from http://www.cao.go.jp/about/pmf_index.html

²⁴ Court of Justice. Lay judge system. (Accessed 30 January 2018) Retrieved from http://www.saibanin.courts.go.jp/topics/saibanin_jissi_jyoukyou.html

2.2 Process and players | The Policy-making process

Although a significant part of Japanese health policy is dictated by revisions made to the fee schedule, bills passed through the legislative process form the structural base of policy, including the government budget. The Japanese fiscal year starts in April and ends in March. The legislative process follows this timeline, with budget bills prioritized so that they can be passed by the start of the next fiscal year each April. Health legislation and other bills are submitted to the Diet by either the Cabinet or by members of the Diet.²⁵

Cabinet deliberations

The Cabinet submits bills to the Diet, and barring emergencies, these bills go through a lengthy process of drafting and deliberations that typically include the following steps.^{26,27}

Problem identification and information gathering

Cabinet members survey stakeholder interests and gauge media reports. To inform discussions, they often consult healthcare practitioners and interview various stakeholders and experts to gather information and sample opinions.

Cabinet council discussions²⁸

Inside the Japanese cabinet there is a large number of councils on topics ranging from space policy to suicide prevention. Councils that hear health policy related discussions include standing councils, such as the Social Security Council and the Committee on Health Insurance, and ad-hoc councils, which are convened to address matters that require a particular level of expertise or to gather a broad range of opinions.

Evaluation of bills by the Cabinet Legislation Bureau

Prior to being introduced at Cabinet Meetings, bills submitted by the Cabinet are wholly evaluated by the Cabinet Legislation Bureau. The Cabinet Legislation Bureau conducts preparatory evaluations of bills drafted, as a matter of course, by government agencies and ministries.²⁹

Evaluation of proposed bills by ruling party

The Evaluation Committee of the ruling party, which has usually been the Liberal Democratic Party over the course of the modern era in Japan, conducts evaluations of bills. Without support from the ruling party, bills will die at this stage. If the ruling party backs a bill, it is circulated in the Cabinet.

Prior to submission to the Diet, a Cabinet decision on the bill is made

Factors considered in Cabinet decisions include the urgency of the bill and how the bill will fit alongside existing laws. Once the Cabinet decides to proceed with a bill, the bill will be submitted to the Diet in February or March by the Prime Minister.

²⁵ Cabinet Legislation Bureau. How a bill becomes a law. (Accessed 30 January 2018) Retrieved from <http://www.clb.go.jp/law/index.html>

²⁶ Cabinet Legislation Bureau. How a bill becomes a law. (Accessed 30 January 2018) Retrieved from <http://www.clb.go.jp/law/index.html>

²⁷ Iwabuchi Yutaka (2013). Handbook of Japanese health policy formulation and structure. Chuohoki Publishing. p.32-41

²⁸ Cabinet Office. Gathering of the deliberative council. (Accessed 30 January 2018) Retrieved from <http://www.cao.go.jp/council.html>

²⁹ Cabinet Legislation Bureau. From the drafting of a bill to the passing of a law. (Accessed 20 April 2018) Retrieved from <http://www.clb.go.jp/law/process.html>

Deliberations in the Cabinet

Other bills are submitted by members of the House of Representatives or by members of the House of Councilors. In addition to the signature of the member who officially proposes a bill, it must also garner the signature of approval of at least a set number of other members. The bill is then given to the Presiding Officer of the proposing member's House. Once a bill enters the Diet, deliberations take place in both the House of Representatives and the House of Councilors. Deliberation usually includes discussions in a Standing Committee, question and answer sessions involving the proposing member or the Prime Minister, and voting at a public hearing or a committee. Bills which survive these processes may pass into law via one of three paths:

- If at least half of all the members of both the House of Representatives and the House of Councilors vote for a bill, it passes
- If one house approves the bill but the other house rejects it, a Conference Committee comprised of members of both houses may be called to develop a proposal on which both Houses can agree
- A bill rejected by the House of Councilors after approval by the House of Representatives may still pass if it is approved once more by the House of Representatives with the two-thirds or more of the members voting in favor of the bill³⁰ (this principle is known as the “superiority of the House of Representatives.” This special privilege exists because the House of Representatives is viewed as more reflective of national opinion given that terms are shorter and that the House of Representatives may be dissolved at any time at the discretion of the Prime Minister.)

Once a bill is approved, the Cabinet informs the Emperor. Following that, the bill must be promulgated into law within 30 days.

Revision of the system for reimbursement of medical fees

Another important process that shapes health policy in Japan is the revision of the NHI fee schedule. This takes place once every two years. For further information about this process, please see Cost Control (Section 7.2).

³⁰ House of Representatives. The prerogatives of the cabinet. (Accessed 1 February 2018) Retrieved from http://www.shugiin.go.jp/internet/itdb_annai.nsf/html/statics/kokkai/kokkai_kengen2.htm

2.3 Process and Players | Health Policy Players

Health policy in Japan, similar to other advanced countries, is a high-stakes arena involving a variety of stakeholders. The following is an overview of the main health policy players in Japan.

Central government and administrative agencies

Public administrative agencies supervise and regulate healthcare through control of the health insurance system. Specifically, government organizations oversee health insurance contracts between the government and healthcare agencies. This power is provided through the 1922 Health Insurance Act.³¹ These organizations are also responsible for regulating pharmaceutical industry practices, including clinical trials, post-market research, and manufacturing. These regulations are created and carried out by various bureaus in the Ministry of Health, Labour and Welfare (MHLW). For example, the evaluation of new drug and medical device applications is the responsibility of the Pharmaceutical and Medical Device Agency (PMDA).³²

Ministry of Health, Labour and Welfare

MHLW, a Ministry of the central government, was originally established in 1938 as the Ministry of Health and Welfare, and came into its current form after it merged with the Ministry of Labour in 2001.³³ As of July 2015, MHLW includes 16 councils, 8 regional bureaus of health and welfare, a labor department in every prefecture, incorporated administrative agencies (including PMDA and the National Hospital Organization, which operates 143 national hospitals as external departments), and government-affiliated corporations such as the Japan Pension Service. In addition, MHLW's head office houses multiple internal bureaus with various functions. The main bureaus that influence health policy include the following:³⁴

Health Insurance Bureau: Plays an active role in bi-annual fee schedule revision and supports healthcare system improvements

Health Policy Bureau: Researches and proposes various policy options in relevant policy areas to respond to the changing demographic and morbidity profile in Japanese society, including healthcare delivery, staff assignment, and health technology

Health Service Bureau: Focuses on regional healthcare, health promotion, measures to address infectious diseases, sanitation, and organ transplantation.

Pharmaceutical and Food Safety Bureau: Establishes policies to ensure the safety and efficacy of pharmaceuticals, medical devices, and cosmetics. It also establishes regulations for hospitals and supervises blood derivatives. This bureau is also charged with addressing the mislabeling of drugs, illicit drug use and stimulants.

Social Welfare and War Victims' Relief Bureau: Addresses a myriad of social welfare issues including homelessness and social relief. This bureau also administers services for families affected by World War II.

Health and Welfare Bureau for the Elderly: Promotes policies related to the Long-term Care Insurance System and welfare services for the elderly in order to support the aging society.

Pension Bureau: Plans and implements the public pension system and corporate pension system.

Labour Standards Bureau: Oversees the health and safety of workers, including working hours, workers' accident compensation, and wages.

³¹ Ministry of Health, Labour and Welfare. Understanding the system of health insurance (Accessed 31 January 2018) Retrieved from http://www.mhlw.go.jp/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/dl/shidou_kansa_01.pdf

³² Pharmaceuticals and Medical Devices Agency. Outline of PMDA. (accessed 31 January 2018) Retrieved from <https://www.pmda.go.jp/files/000219906.pdf>

³³ Ministry of Health, Labour and Welfare. The beginnings of the Ministry of Health, Labour and Welfare

³⁴ Ministry of Health, Labour and Welfare. Main work (Duties). (Accessed 31 January 2018) Retrieved from <http://www.mhlw.go.jp/kouseiroudoushou/shigoto/>

Equal Employment, Children and Families Bureau: Plans policies that support working families and the well-being of children.

Pharmaceuticals and Medical Devices Agency (PMDA)

PMDA, established in 2004, is an independent administrative agency³⁵, responsible for evaluating the quality and effectiveness of new drug and medical device applications, post-market safety, and addressing damages related to adverse health effects. The agency is comprised of multiple offices, including the Office of International Programs, which liaises with non-Japanese applicants and inquiries; the Office of Regulatory Science, which works to build Japan's regulatory science capacity, and the Office of Cellular and Tissue-based Products, which focuses on biologics and tissue-engineered medical products. Through various policies and organizational strategies, PMDA has been successful at bringing the average review time of standard review products down from 22 months in 2008 to 11.3 months as of the end of August 2015. The average review time of priority review products went from 15.4 months in 2008 to 6.1 months in 2012, and as low as 8.7 months as of the end of August of 2015.³⁶

Central Social Insurance Medical Council

The Central Social Insurance Medical Council, or Chu-i-kyo in Japanese, is run by staff of MHLW's Health Insurance Bureau (HIB) and convenes to advise the Minister of Health, Labour and Welfare on health insurance and health services. The Council includes representatives from the payer side, the provider side and academics representing the public interest. While it conducts various discussions throughout the year, its main role is to debate and set fee schedule revisions for medical services and pharmaceuticals and National Health Insurance (NHI) drug prices.³⁷

Ministry of Finance Budget Bureau

The Budget Bureau (BB) of the Ministry of Finance overseas subsidies to NHI through its jurisdiction over the national budget. It is one of the foremost players in healthcare policy. The subsidies, which are in essence government spending, are comprised of revenue from taxes as well as funds borrowed by the government. The BB has the most influence during the bi-annual fee-schedule and drug-price revision, when it works with MHLW's HIB to establish the global rate of price revision. As stakes are high in this process, revisions involve lengthy negotiations with a variety of actors.³⁸

<Column> Lining up from the early morning to see Chu-i-kyo

Some will say that if there is one terms non-Japanese people should remember related to health policy in Japan, it is "Chu-i-kyo," the abbreviated name for the Central Social Insurance Medical Council (CSIMC). Chu-i-kyo is the most important government council involved in health policymaking. Every stakeholder in the field watches the movement of this Council closely. Regulations stipulate that it publish its meeting proceedings and that meetings be open to the general public. Chu-i-kyo attracts great attention once every two years between Fall and February, just before the fee schedule revision, which takes place in April. During this short time period, Council members engage in detailed discussions around the fee schedule revision. In order to stay informed of discussions, members of the media, the pharmaceutical industry, and the healthcare sector usually line up from the very early morning to get a ticket to sit in during meetings (tickets are handed out on a first-come, first-served basis). It is common to see the Council's meeting room, which comfortably seats 10 people, filled with over 100 people up to 3 hours before a meeting is scheduled to begin.

³⁵ Pharmaceuticals and Medical Devices Agency. (PMDA) (accessed 11 October 2017) Retrieved from <https://www.pmda.go.jp/about-pmda/outline/0001.html>

³⁶ Pharmaceuticals and Medical Devices Agency. Our achievements up until now (2016) and challenges for the future. (accessed 11 October 2017) Retrieved from <https://www.pmda.go.jp/files/000215764.pdf>

³⁷ Ministry of Health, Labour and Welfare. About the Central Social Insurance Medical Council. (accessed 30 January 2018) Retrieved from <http://www.mhlw.go.jp/shingi/2005/03/dl/s0309-4e3.pdf>

³⁸ Ikegami Naoki (2014) Universal Health Coverage for Comprehensive and Sustainable Development – Synthesis of research in 11 countries. Japan Center for International Exchange. (accessed 29 January 2018) Retrieved from <http://www.icie.org/japan/i/pdf/pub/publst/1452/1452all.pdf>

The Liberal Democratic Party

The Liberal Democratic Party (LDP) has been at the forefront of health policy since the end of the occupation by U.S. Forces in the early 1950s. During that time of political transition, healthcare emerged as a focal point of debate and the LDP, the ruling party then, took the lead by pushing for universal health coverage, thus garnering a wide support base. Through amendments to the National Health Insurance Act in 1958, which aimed to expand health insurance coverage, the LDP established systems of insurance for the unemployed, retired, self-employed and irregularly employed in every municipality throughout Japan, achieving universal health coverage in the process.³⁹ Since then, the LDP has continued to play an active role in health policy through legislative action and political leadership built atop relationships with bureaucratic circles and interest groups. Since the start of Japan's current healthcare system, the LDP has dominated politics and held the majority in the Diet almost the entire time, with the exception of an 11-month period between 1993 and 1994 and the 3 years between 2009 and 2011.

The Japan Medical Association⁴⁰

Approximately 55% of physicians in Japan are members of the Japan Medical Association (JMA), by far the most prominent health policy interest group. The JMA works closely with bureaucrats, government agencies, and the majority party (which, throughout modern history, has overwhelmingly been the LDP) to protect physician autonomy and professional interests.

The JMA has seats on the Central Social Insurance Medical Council, which sets the NHI fee schedule. In addition to official appointments, the JMA regularly issues informal recommendations and engages in active lobbying, which exerts a strong influence on health policy-related legislation. However, even when opposed to certain proposed revisions, it is not uncommon for it to make concessions or compromises to ensure smooth relations with the government. For example, during the Koizumi Administration (2001-2006), attempts to introduce market-based approaches into the healthcare field by lifting the ban on the mixed billing and approving management of hospitals by investment institutions were met with major pushback from the JMA. Although no major reforms materialized, this opportunity for reform did conclude with some minor changes to the existing system.

<Column> 3 Doctors' Association

As is the case in other countries, physician groups have a large amount of influence on health policy in Japan. In Japan, the Japan Medical Association, the Japan Dental Association, and the Japan Pharmaceutical Association are referred to collectively as the "3 Doctors' Association" because of the unrivaled presence these groups have amongst health-related organizations. There are nearly 50 other professional associations, including the Japanese Nursing Association, the All Japan Hospital Association and the Japan Pharmaceutical Manufacturers Association, that work to maintain favorable relationships with the government and the ruling party in order to affect the policy environment.

Prefectural governments

The Medical Service Act stipulates that prefectural governments oversee medical facilities and providers within the prefecture. In contrast with the administrative agencies of the government, which supervise the contracts and payment systems, prefectural governments monitor adherence to regulations related to the establishment of medical facilities, staffing, and the management of pharmaceuticals and other products. This role for prefectural governments was introduced in the 1985 revision of the Medical Service Act. Prefectural governments also have jurisdiction over the establishment of healthcare centers, and measures addressing diseases and sanitation. Health centers are also established by government-designated cities and special wards.⁴¹

³⁹Ikegami Naoki (2014) Universal Health Coverage for Comprehensive and Sustainable Development – Synthesis of research in 11 countries. Japan Center for International Exchange. (accessed 30 January 2018) Retrieved from <http://www.jcie.org/japan/j/pdf/pub/publst/1452/1452all.pdf>

⁴⁰ Ikegami Naoki (2014) Universal Health Coverage for Comprehensive and Sustainable Development – Synthesis of research in 11 countries. Japan Center for International Exchange. (accessed 29 January 2018) Retrieved from <http://www.jcie.org/japan/j/pdf/pub/publst/1452/1452all.pdf>

⁴¹ Ministry of Health, Labour and Welfare. Regional healthcare. (accessed 1 February 2018) Retrieved from <http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/tiiki/index.html>

Municipal governments

Currently, local governments such as municipal town halls set public health policy related to disease prevention and family health through community health centers. The 1982 Healthcare for the Aged Act increased municipal involvement by asking municipal governments to increase health services for the elderly, including health instruction and health screenings. The 2002 Health Promotion Act called for municipal governments to actively participate in community health planning.⁴²

⁴² Ministry of Health, Labour and Welfare. Health Promotion Act – Background Information. (accessed 1 January 2018) Retrieved from <http://www.mhlw.go.jp/shingi/2004/12/dl/s1202-4g.pdf>

3.1 The Health Insurance System | Japan's Health Insurance System

Overview of the health insurance system

Japan's constitution, established in May of 1947, clearly states that citizens have the right to health, and that the advancement and promotion of social welfare, social security, and public health are within the scope of government responsibilities [i]. In 1961, as a result of government-led social welfare measures, Japan achieved universal health coverage (UHC).⁴³

Characteristics of Japan's UHC system are as follows:

Enrollment in public health insurance is compulsory, regardless of citizenship, for all those who have resided in Japan for three months or more. Rather than being freely selected by enrollees, public health insurance schemes are designated according to employment status, age, and residence. If an enrollee is neither the head of household nor eligible through his or her own employer, then the scheme is designated based on the head of household's employment status, age, and residence.

Regardless of the health insurance scheme in which residents of Japan are enrolled, they are free to choose their own healthcare providers as well as their frequency of treatment. In Japan, this system is referred to as a "Free Access System," and according to Free Access, as long as residents hold proof of insurance, they may receive necessary medical services when sick or injured for a fixed contribution rate.⁴⁴

As a result, out of convenience, some patients seek outpatient visits at secondary emergency medical facilities mainly intended for patients in need of hospitalization and surgery, despite having only minor illnesses, and such "visits of convenience" have been recognized as problematic. In order to safeguard the medical sector from exhaustion due to issues such as human resource shortages, primary care physicians and flat, per-visit copayments are being discussed as ways of helping patients to select appropriate occasions for treatment that are in line with the functions of each provider.⁴⁵

[i] Article 25 of the Japanese Constitution states that "All people shall have the right to maintain the minimum standards of wholesome and cultured living" and that "The State shall use its endeavors for the promotion and extension of social welfare and security, and of public health."

<Column> Free Access and Freedom of Practice

Patients are free to receive care from the provider of their choice. For example, a man working at a company in Tokyo can make an outpatient visit to a specialist at a university hospital near his office during his spare time and later that same weekend be seen by a physician at a clinic near his home in Kanagawa Prefecture. According to guidelines, referral letters are required for outpatient visits at large hospitals; however, in most cases, patients are free to see specialists at large hospitals as long as they are willing to pay additional fees of a few thousand yen. Physicians also have freedom of practice. Moreover, if physicians have acquired medical licenses, they may exercise freedom by practicing in any specialties regardless of whether or not they hold specialized certifications. It is possible, for example, for a surgeon to practice as an "Internist/Orthopedic Surgeon," and it is not uncommon to see signs outside clinics that list multiple specialties.

⁴³ Ministry of Health, Labour and Welfare "Annual Health, Labour and Welfare Report 2007" <http://www.mhlw.go.jp/wp/hakusyo/kousei/07/dl/0101.pdf> (accessed 25 January 2018)

⁴⁴ Ministry of Health, Labour and Welfare "Japan's Health Insurance System" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000172084.pdf> (accessed 25 January 2018)

⁴⁵ Cabinet Office, Government of Japan "The Current Situation Regarding the Primary Care System" http://www8.cao.go.jp/kisei-kaikaku/kaigi/meeting/2013/wg2/kenko/131009/item3_5.pdf (accessed 25 January 2018)

Insurance benefits and patient cost-sharing

Regardless of which of the three public health insurance schemes in which one is enrolled, benefit packages essentially remain the same. Enrollees are unable to select schemes themselves, so even though slight differences do exist between benefits, such as add-ons for disease prevention and health promotion, these differences do not influence enrollment. In all three schemes, benefits cover services such as hospitalization, outpatient visits, transportation costs for psychiatric treatments, prescription medications, home-visit nursing, and dental care.

Co-insurance rates for medical costs remain the same across all insurance schemes, and are designated, instead, depending on age and employment status. Co-insurance for residents under 70 years of age is set at 30%. It is also set at 30% for those aged 75 and over but still earning incomes comparable to the current workforce. Co-insurance is set at 20% for children under 6 (prior to compulsory education), and it is also set at 20% for residents 70 to 74, while it is set at 10% for low-income earners aged 75 and over.⁴⁶

Overview of the High-Cost Medical Expense Benefit System

In order to prevent catastrophic medical expenses from overburdening household finances, the High-Cost Medical Expense Benefit System subsidizes medical costs in excess of monthly, out-of-pocket (OOP) thresholds. These thresholds vary depending on the ages and incomes of beneficiaries. For example, in the case of an enrollee aged 69 years or under earning an approximate income of between 3.7 and 7.7 million yen, the monthly ceiling or maximum payment is calculated as $[80,100 \text{ yen} + (\text{medical costs} - 267,000 \text{ yen}) \times 1\%]$. The High-Cost Medical Expense Benefit System plays a major role in ensuring Financial Risk Protection (FRP) within the healthcare system.⁴⁷ High-cost medical expense subsidies in FY2013 totaled around 1.6772 trillion yen for people under age 75 and totaled around 5.429 billion yen for people 75 and over. In the 10-year period from 2004 to 2013, those totals rose by factors of approximately 1.56 and 1.65 respectively. When viewed as a whole, total allowances for high-cost medical expenses are increasing.⁴⁸

System of insurance premiums

The methods for calculating insurance premiums vary depending on the public health insurance scheme, so premiums paid by enrollees also vary. In schemes such as those managed by Health Insurance Societies and the Japan Health Insurance Association (JHIA), employers are responsible for half the cost of premiums. Health Insurance Society and JHIA premiums are calculated by multiplying the premium contribution rate by the average amount of monthly remuneration (such as monthly pay, delimited at reasonable intervals, received by an insured person from an employer). Premium contribution rates vary from Health Insurance Society to Health Insurance Society and from one branch of the JHIA to another.

The methods for calculating premiums within the National Health Insurance (NHI) system vary according to region. Premiums are determined based on four factors—income (levied on the head of household's income), assets (levied on the head of household's assets), equality (calculated per enrollee), and equity (calculated per household).

In this way, premiums vary depending on the enrolled health insurance scheme, but in general, premiums rise in relation to income, since they are calculated based on factors such as income. Premiums cover not only the benefits of enrollees themselves, but also the benefits of those in the age 65 to 74 bracket as well as the 75 and over bracket. Consequently, because there are gaps in the income levels of enrollees among health insurance schemes, fiscal adjustments are undertaken among schemes to stabilize financial resources.

⁴⁶ Ministry of Health, Labour and Welfare "Overview of Our Country's Healthcare System" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000172084.pdf> (accessed 1 September 2017)

⁴⁷ Ministry of Health, Labour and Welfare "To Users of the High-Cost Medical Expense Benefit System" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000161153.pdf> (accessed 1 September 2017)

⁴⁸ Ministry of Health, Labour and Welfare "Re-examination of the High-Cost Medical Expense Benefit System" http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000138069.pdf (accessed 16 October 2017)

Overview of health insurers

Japan's over 3,000 insurers can roughly be divided based on the three types of insurance that they provide—employer-based health insurance, residence-based National Health Insurance (NHI), and health insurance for people aged 75 and over. Health insurance for people 75 and over is primarily supported by public funding as well as by contributions from employer-based health insurance and NHI.

—Employer-Based Health Insurance

Employer-based health insurance can be subdivided into 3 schemes. The first of these schemes is managed by Health Insurance Societies, aimed mainly at large companies, provided by over 1,300 insurers, and eligible for public subsidies in the case of financial difficulties. The second scheme is managed by Mutual Aid Associations (MAAs), aimed at government workers, and ineligible for public subsidies. The third scheme is administered by the Japan Health Insurance Association (JHIA) and aimed at employees of small- to medium-sized companies. Besides enrollee premiums, the majority of the JHIA's financial resources are comprised of Health Insurance Society premiums and public funding. Aspects such as the number of enrollees and standard premiums vary by scheme.⁴⁹

Health Insurance Societies were established as public corporations under the National Health Insurance Act.⁵⁰ Societies are organized by single companies (Single Health Insurance Societies) as well as by business owners within the same industry (General Health Insurance Societies). Enrollees in Health Insurance Society plans numbered 29.17 million at the end of August, 2016, and there were 1,357 associations as of April 1, 2017. The JHIA was established based on the National Health Insurance Act as an insurer for the employees and families of small- to medium-sized businesses that are unable to establish Health Insurance Societies. Enrollees in JHIA plans numbered 37.18 million at the end of August 2016. Premium levels vary among regional branch offices. In cases where a Health Insurance Society becomes unable to operate and disbands due to reasons such as financial difficulties, beneficiaries thus far enrolled in the society-managed plan are then enroll in a JHIA association-managed plan. In other words, the JHIA assumes the role of a safety net for employer-based health insurance. Mutual Aid Associations were established based on Mutual Aid Laws as insurers for national government workers. At the end of March, 2014, there were eighty-five MAAs, and enrollees numbered 8.91 million. Similar to Health Insurance Societies, premium levels vary depending on the MAA in which one is enrolled.

—Residence-Based National Health Insurance

The residence-based National Health Insurance (NHI) system is the health insurance scheme that covers the self-employed, unemployed, and retirees under 75 years of age. In other words, the NHI acts as the medical safety net for sustaining the health of residents in the sense that it insures those not otherwise enrolled in insurance schemes. Management of the NHI was shifted from the national to the prefectural level in 2018, and the system is currently administered at the municipal level. The stated goal of this shift was to strengthen the financial foundations of the NHI, which continues to run a deficit, by placing fiscal management responsibility in the hands of prefectural governments, thus securing stable fiscal management and efficient business operations. Under the current system, NHI enrollees pay premiums, but 50% of the actual costs for benefits are covered by public funding. The system is financially unstable and faces structural challenges, including a high average enrollee age composition, low average enrollee income levels, and low average enrollee payment rates (both premiums and taxes).⁵¹

—Health Insurance for the Elderly

The Medical Care System for the Advanced Elderly, as mentioned in Section 1, was introduced in 2008. All people aged 75 and over are obliged to enroll, and all enrollees become insured individuals, with no distinction between

⁴⁹ National Federation of Health Insurance Societies "Healthcare Coverage Seen Through Charts, 2017 Edition," Gyosei Corporation, p.57-59.

⁵⁰ National Federation of Health Insurance Societies "Basics of the Health Insurance System" http://www.kenporen.com/health-insurance/m_knowledge/ (accessed 25 January 2018)

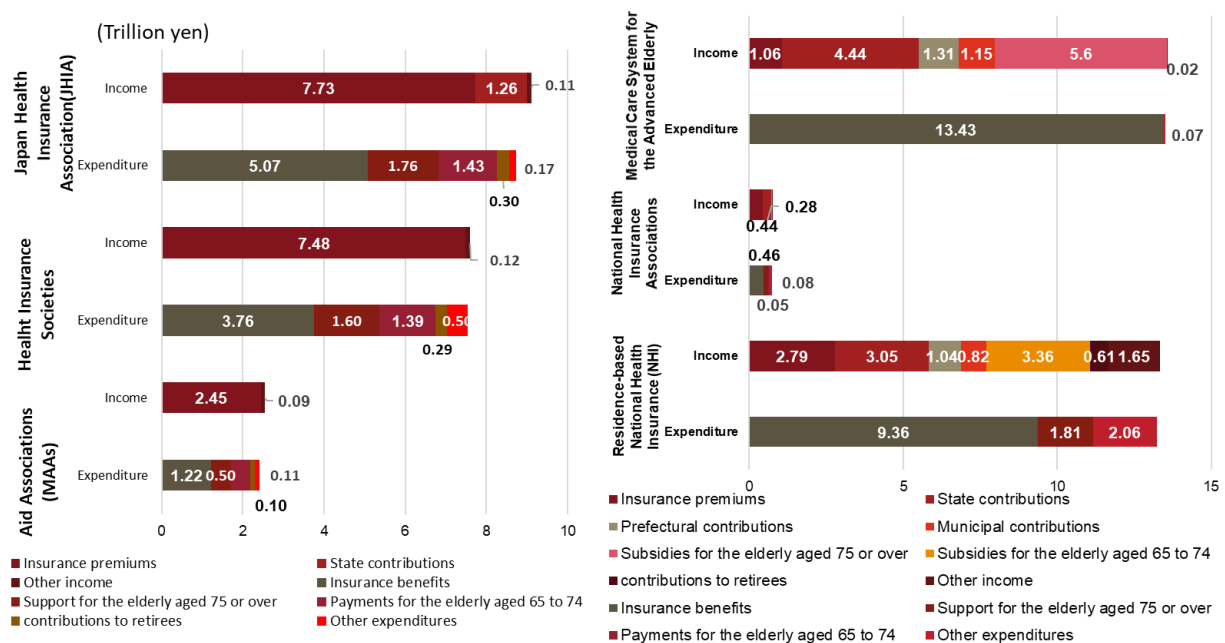
⁵¹ Ministry of Health, Labour and Welfare "Reform of Health Insurance System" https://www.kantei.go.jp/jp/singi/syakaihosyou_kaikaku/dai4/siryou2.pdf (accessed 20 October 2017)

supporters and dependents. The system is administered at municipal as well as prefectural levels. To promote transparency and accountability regarding the expenses and medical costs that accompany the aging of the population, the system for people 75 and over has been made virtually independent from the NHI system. Premiums are calculated at the prefectural level based on health expenditures from the previous two years and are deducted from the individual pensions of enrollees. Since premium payments from enrollees themselves only cover around 10% of medical costs, the Medical Care System for the Advanced Elderly is supported by public subsidies along with fiscal adjustments from the two aforementioned insurance schemes.⁵²

Income and expenditures by health insurance scheme

As shown in Figure 3-1-1, a process of fiscal adjustments takes place among insurers. Contributions for people aged 75 and over, payments for people ages 65 to 74, and contributions to retirement funds are designated as expenditures of the Japan Health Insurance Association (JHIA), Health Insurance Societies, and Mutual Aid Associations (MAAs). These expenditures are subsidies for people aged 75 and over from within the income of the Medical Care System for the Advanced Elderly, subsidies for people ages 65 to 74 from within the income of the residence-based NHI, and retirement premiums. As Figure 3-1-1 also shows, the ratio of income (comprised of insurance premiums and state liability funds) to expenditures (comprised of insurance benefit payments) varies among insurers. As can also be seen, the portion of income within the Medical Care System for the Advanced Elderly and the National Health Insurance (NHI) system that is covered by the National Treasury greatly exceeds the portion covered by insurance premiums. In other words, the fiscal management situation is so severe that no other choice remains but to rely on the National Treasury.

Figure 3-1-1: Income and expenditures in the health insurance system, FY2014



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on basic data extracted from the "2014 state of national medical expenditures" report by the Ministry of Health, Labour and Welfare

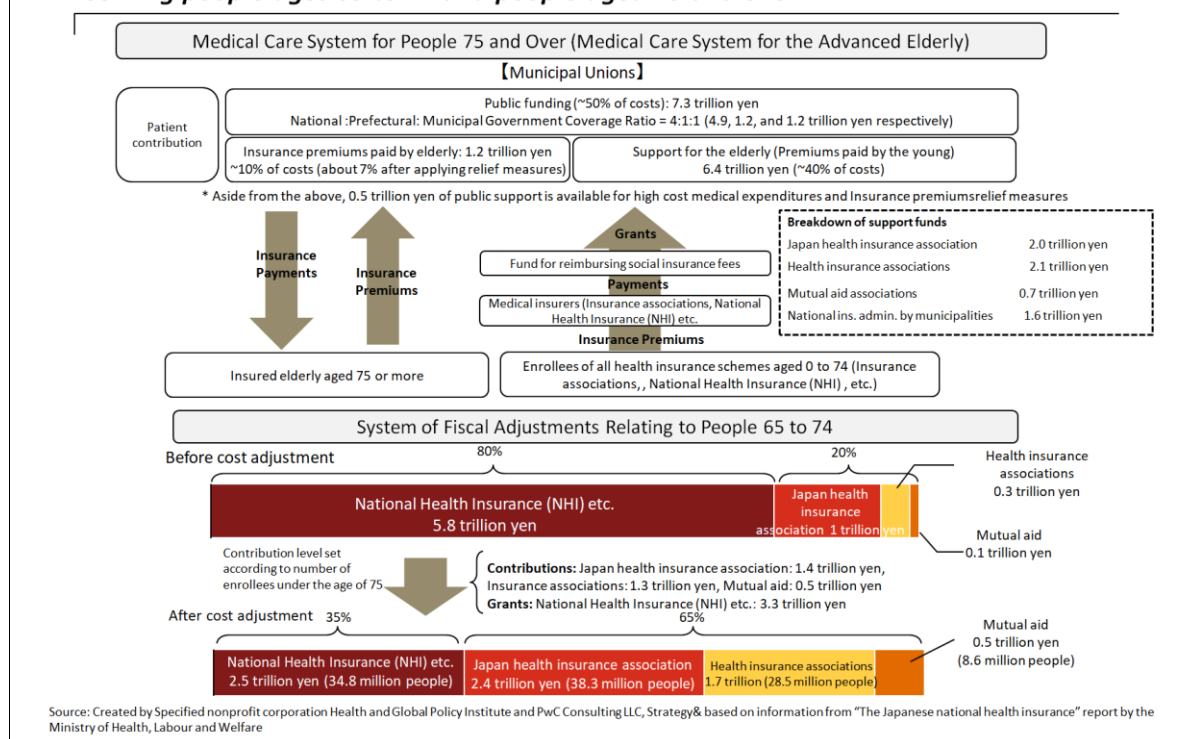
⁵² Ministry of Health, Labour and Welfare "Our Country's Health Insurance"

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html (accessed 20 October 2017)

Structure of the medical care system serving people aged 65 and over

In terms of fiscal adjustments within the medical care system for the elderly, as shown in Figure 3-1-2, about 50% of the financial resources for the Medical Care System for the Advanced Elderly (75 and over) are covered by public funding (National : Prefectural : Municipal = 4:1:1), 40% are covered by contributions from individual insurers (i.e. paid from the premiums of the working class), and around 10% are covered from premiums paid by enrollees themselves. The scale of medical expenses for those aged 75 and over has reached 16.8 trillion yen (FY2017 base benefit expenses of 15.4 trillion yen combined with out-of-pocket (OOP) patient expenses of 1.3 trillion yen).⁵³ In principle, contributions paid out of the premiums from the labor force are determined proportionally according to each insurer's number of enrollees aged zero to 74. Since this per-capita contribution depends on the number of enrollees, insurers with weak financial standing shoulder a heavy burden. Therefore, in order to burden each insurer based on their financial capacity, the apportionment of the required contribution from each insurer has been gradually adjusted, with the proportion of the contribution required from employer-based insurers starting at one-half of what they should owe in FY2015, then rising to two thirds in FY2016, and eventually to the total amount in FY2017.⁵⁴

Figure 3-1-2: Fiscal adjustment mechanism used for the health insurance systems serving people ages 65 to 74 and people aged 75 and over



⁵³ Ministry of Health, Labour and Welfare "Our Country's Health Insurance"

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html (accessed 20 October 2017)

⁵⁴ Ministry of Health, Labour and Welfare "Expense Burdens (Total Fee Allocation)" http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000140159.pdf (accessed 25 Jan 2018)

To resolve imbalances among the fiscal burdens shouldered by insurers that result from the unequal distribution of enrollees ages 65 to 74, each insurer's burden is fiscally adjusted based on the proportion of the population ages 65 to 74 that they enroll. As a result of these fiscal adjustments, unlike in the Medical Care System for the Advanced Elderly, people ages 65 to 74 remain insured under the same various schemes in which they were previously enrolled. As shown in Figure 3-1-2, prior to fiscal adjustment, the benefit payments for those ages 65 to 74 are initially shouldered 80% by schemes such as residence-based National Health Insurance (NHI) and 20% by the other insurers, but this imbalance is fiscally adjusted among insurers such that in the end, benefits are shouldered 35% by schemes such as residence-based NHI, and 65% by the other insurers.⁵⁵

System of publicly insured medical services

As previously mentioned, under Japan's system of Universal Health Coverage (UHC), citizens are enrolled in at least one of the public health insurance schemes. The following section explains Japan's system of insurance-applicable services as well as the payment system for incurred medical expenses. The premise of this payment system is a medical service fee scheme. Medical service fees are the fees received by insured healthcare providers as compensation for publicly insured medical services and pharmaceuticals. After a patient visits a provider and pays the co-insurance portion of the incurred medical expenses (the total medical service fee), the provider then requests the remaining portion of the medical service fee from the insurer.

As also described in detail in Section 7, medical service fees are set based on discussions held by the Ministry of Health, Labour and Welfare at the Central Social Insurance Medical Council, and a fee review is conducted once every 2 years. Medical service fees are scored using a system of points, with one point valued at 10 yen.⁵⁶

⁵⁵ Ministry of Health, Labour and Welfare "Our Country's Health Insurance"

http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryouhoken/iryouhoken01/index.html (accessed 20 October 2017)

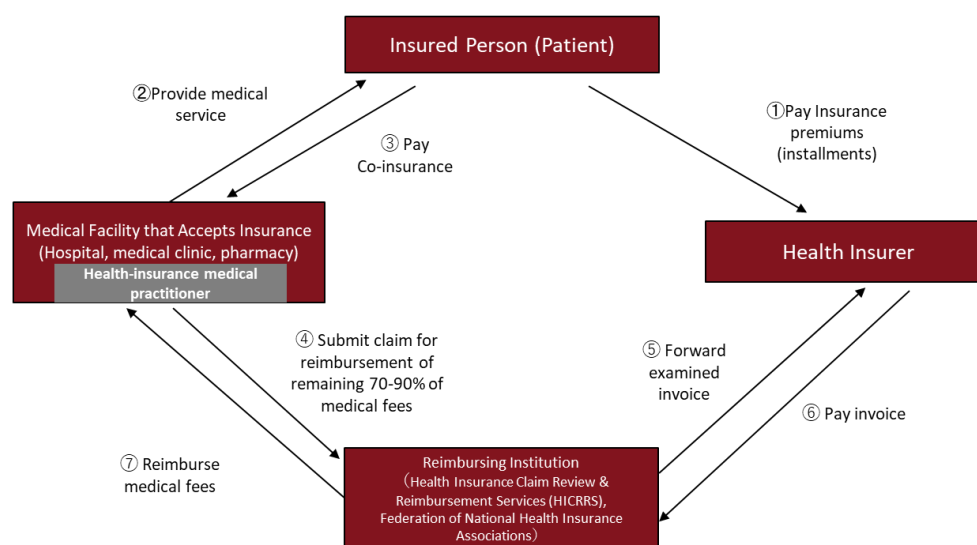
⁵⁶ Ministry of Health, Labour and Welfare "The Medical Service Fee Scheme" <http://www.mhlw.go.jp/bunya/iryouhoken/iryouhoken01/dl/01b.pdf> (accessed 25 January 2018)

Figure 3-1-3 shows the flow of charges and payments for medical services covered by public insurance. When a patient carrying proof of insurance visits a medical provider, they pay co-insurance of 10% to 30% to the provider for received treatments based on their age and income. The 70% to 90% of the incurred medical fees that are excluded from co-insurance are covered by public funding from sources such as paid insurance premiums and taxes. Providers covered under the health insurance system submit claims for reimbursement of this 70% to 90% to Claims Review and Reimbursement Organizations (CRROs) such as the Health Insurance Claims Review & Reimbursement Services (HICRRS) and the National Federation of Health Insurance Societies (Kenporen). CRROs review whether insurance claims are reasonable, charge insurers for the remaining portion of medical service fees to be paid to the provider, receive these payments from health insurers, and pay them as reimbursement to providers. In other words, the role of CRROs is to review medical service fee statements (detailed insurance claim receipts) submitted by medical providers and process medical service fee payments based on the results of those reviews.

<Column> Insurer functions are entrusted to Claims Review and Reimbursement Organizations?

Claims Review and Reimbursement Organizations (CRROs) established in each prefecture are in charge of sending invoices to insurers and receiving reimbursement for providers. Under this system, after a service is provided and co-insurance is received from the patient, the provider requests reimbursement from the insurer for the remaining portion of the medical service fee. In order to facilitate payment of medical service fees, the Health Insurance Claims Review & Reimbursement Services (HICRRS) and the National Federation of Health Insurance Societies (Kenporen) have established prefectural branches that handle the processing of medical service fee payments.

Figure 3-1-3: Flow of charges and payments for publicly insured medical services



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "System of reimbursement of medical fees" report by the Ministry of Health, Labour and Welfare

CRROs confirm whether or not services provided to patients conform to insurance rules (E.g. Rules for Professionals in Charge of Insurance-Covered Healthcare Services and related notices). One issue that has been raised is that although all claims must be reviewed according to the same set of rules, reimbursement disparities

remain among prefectural branches of CRROs because criteria for determining the validity of claims often vary by branch.⁵⁷

⁵⁷ Ministry of Health, Labour and Welfare "Improving Operational Efficiency of the Payment Fund / Development Plan—Schedule Overview"
<http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000169999.pdf> (accessed 16 October 2017)

3.2 The Health Insurance System | Japan's Long-Term Care Insurance System

Overview of the Long-term Care Insurance System

The Long-term Care Insurance System was launched in 2000 as a system for society as a whole to support the long-term care of the elderly. Municipalities operate as insurers, and all citizens over the age of 40 are covered by this system. In comparison to other countries, this system is quite generous in terms of the levels of coverage and benefits. More than 5 million people were eligible for Long-term Care Insurance as of April 2016.⁵⁸

Foundations of the Long-term Care Insurance System

The foundations of Japan's Long-term Care Insurance are described in detail in Section 1. Under the Elderly Welfare System that existed in the past, municipal governments were given the final say in the selection of services, and since users could not select services, the content of services tended to be uniform. In addition, since service fees were based on a patient's ability to pay, people with middle- and high-level incomes shouldered heavy burdens, and general hospitals began to face problems related to long-term hospitalizations for long-term care. Along with the rapid aging of the population, the number of people requiring long-term care as well as the length of care itself increased, and long-term care needs grew greater and greater. At the same time, the status quo in which families traditionally met the needs of the elderly began changing, with shifts toward nuclear families and the aging of the generation that provided care.⁵⁹

After taking into account issues and changes such as these, Japan developed the Long-term Care Insurance System as a way for society as a whole to support the long-term care of the elderly.

Basic principles of the Long-term Care Insurance System

- Independence support: To go beyond simply providing necessary long-term care and also support the independence of elderly people.
- User-oriented system: To provide users integrated access to health and welfare services from diverse entities at their own discretion.
- Social insurance system: To employ a social insurance scheme with a clear relationship between benefits and burdens.

Long-term Care Insurance enrollees and premiums

Enrollees in Long-term Care Insurance are divided into two categories—Those aged 65 and over (Category 1 Insured) and those ages 45 to 64 who are concurrently enrolled in other medical insurance schemes (Category 2 Insured).

- Category 1 Insured: Eligible for services regardless of whether they receive Certification for Long-term Care Need or Certification for Support Need.
- Category 2 Insured: Eligible for services only after they receive Certification for Long-term Care Need or Certification for Support Need due to aging-related diseases (specified diseases).

⁵⁸ Ministry of Health, Labour and Welfare (2016) "A survey on the state of current long-term care benefits" <http://www.mhlw.go.jp/toukei/saikin/hw/kaigo/kyufu/16/index.html> (accessed 19 November 2017)

⁵⁹ Ministry of Health, Labour and Welfare "The current and future role of the public Long-term Care Insurance System" http://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/201602kaigohokenntoha_2.pdf (accessed 19 November 2017)

At the end of FY2015, Category 1 Insured numbered 33.82 million people, and Category 2 Insured numbered 42.04 million people (according to retrospective, monthly averages published in 2017).^{60,61}

Category 1 enrollees (age 65 and over) pay their health insurance and Long-term Care Insurance premiums separately. Premiums and insurance rates are set by municipalities and pegged to nine standardized levels of income.⁶² For Category 2 enrollees (ages 40 to 64), health insurance and long-term care insurance premiums are paid together in a lump sum.⁶³

<Column> Why age 40 and over?

Surrounding the establishment of the Long-term Care Insurance System, there was a great deal of debate centering on the justification behind targeting people aged 40 and over. Amidst various opinions, there was support for targeting people aged 20 and over or 60 and over, but it was pointed out during consultations on the Long-term Care Insurance System in 1996 at the Council on Health and Welfare for the Elderly that once people pass the age of 40, the likelihood that they will have to care for their parents and thus need social support increases. As a result, the decision was made to enroll people aged 40 and over since long-term care costs should be supported by society as a whole. It was through such discussions that the current system took shape. (MHLW, 2006)

⁶⁰ Ministry of Health, Labour and Welfare (2015) “Annual report on Long-term Care Insurance”

http://www.mhlw.go.jp/topics/kaigo/osirase/jigyoku/15/dl/h27_gaiyou.pdf (accessed 25 January 2018)

⁶¹ Ministry of Health, Labour and Welfare “Long-term Care Insurance premiums for the Category 2 Insured persons”

http://www.mhlw.go.jp/topics/kaigo/osirase/jigyoku/15/dl/h27_hihokensha.pdf (accessed 25 January 2018)

⁶² Ministry of Health, Labour and Welfare “Overview of the FY2018 Budget (Draft) (Health and Welfare Bureau for the Elderly)”

<https://www.mhlw.go.jp/wp/yosan/yosan/18syokanyosan/dl/gaiyo-13.pdf> (accessed 6 July 2018)

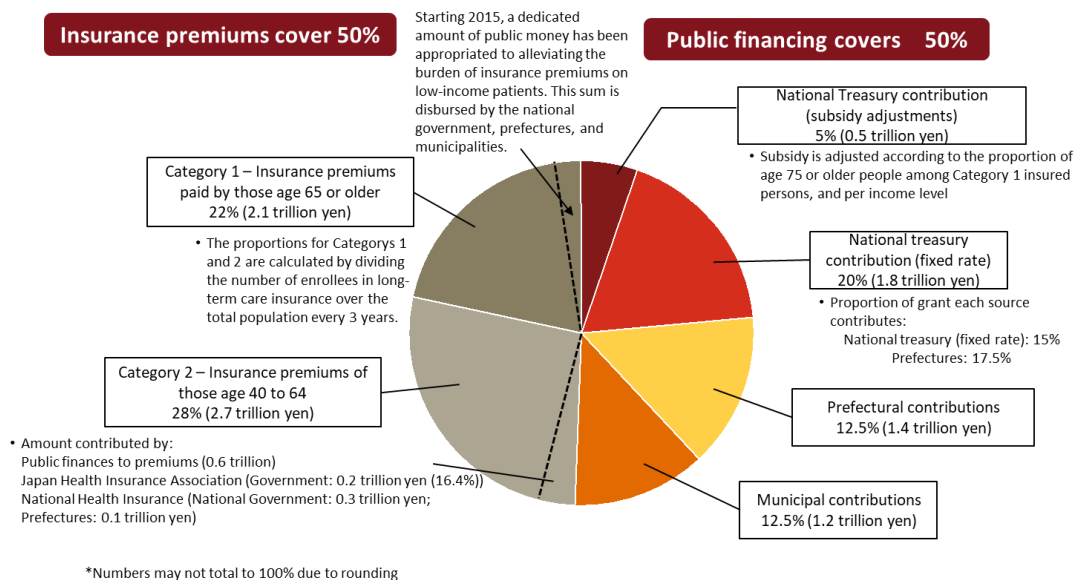
⁶³ Ministry of Health, Labour and Welfare “The Long-term Care Insurance System” http://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/2gou_leaflet.pdf (accessed 21 November 2017)

Cost of Long-term Care Insurance

As shown in figure 3-2-1, half of the financing for Long-term Care Insurance comes from enrollee premiums, while the other half comes from public funding. The budget for long-term care benefit pay-outs was set at 9.6 trillion yen in FY2016. Funds were sourced from Category 1 premiums (2.1 trillion yen), Category 2 premiums (2.7 trillion yen), the national treasury (2.2 trillion yen), prefectures (1.4 trillion yen), and municipalities (1.2 trillion yen). Similar to medical expenses, long-term care expenses are increasing annually along with increasing benefit costs, and this trend is expected to continue in the future given the ageing of society in Japan.⁶⁴

Figure 3-2-1: The framework and scope of funding for Long-term Care Insurance

(FY2016 Budget (Draft): Cost of Long-term Care Insurance Benefits: 9.6 trillion yen (Total funding base: 10.4 trillion yen)



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "Current state of nursing-care insurance system and its future role" report by the Ministry of Health, Labour and Welfare

Imbalances in funding and financial burdens exist among prefectures as a result of the fact that prefectures with high proportions of people over age 75 face rising benefit pay-outs, and prefectures with low average income levels face falling revenues. Financial actions are being taken, with five percent out of the 26% share of funding provided by the National Treasury subject to fiscal adjustments. The system of adjustments bears close resemblance to initiatives within the Medical Care System for the Elderly (explained in Section 1.2) in the sense that both systems are designed to help reduce imbalances among the fiscal resources of different insurers.

⁶⁴ Ministry of Health, Labour and Welfare "The current and future role of the public Long-term Care Insurance System" http://www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/201602kaigohokenntoha_2.pdf (accessed 21 October 2017)

Usage of care services and the Certification of Long-term Care Need

To use long-term care services, applications are submitted to municipal government offices or Comprehensive Community Support Centers. To qualify, applicants must receive Certification of Long-term Care Need or Certification of Needed Support. Upon receipt of certification, care managers prepare plans for applicants, enabling them to use a variety of services.

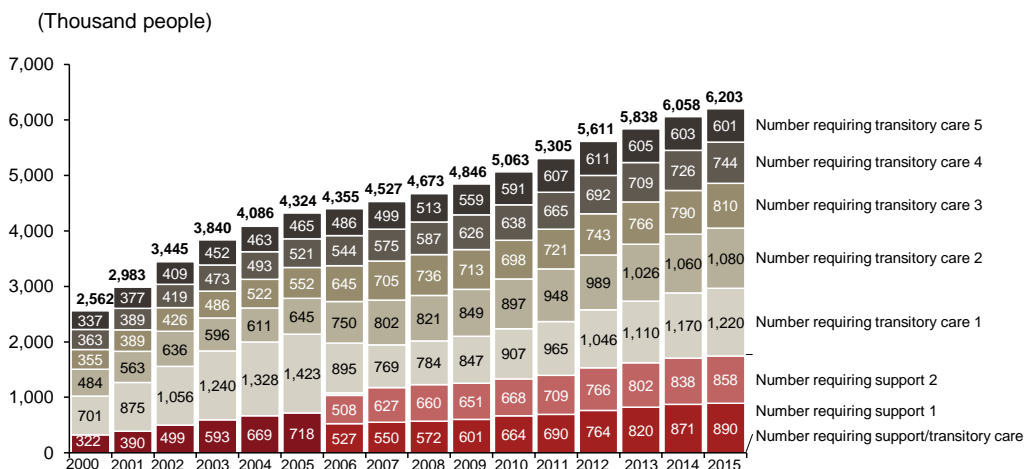
A person's level of required care (classified as Preventative Support Level 1 or 2, or Long-term Care Level 1 through 5) is determined by a committee of specialists that takes into consideration a written diagnosis from an attending physician and an on-site survey that addresses 74 items related to the activities of the person's daily life. The appropriateness of the person's level of care is then re-evaluated every two years or following marked deterioration in health.⁶⁵ The yearly trend in the number of people requiring care is shown in figure 3-2-2.

To address the fact that demand for long-term care does not decrease and to curb the continual growth in the population requiring light degrees of care (Preventative Support Level 1 / Long-term Care Level 1), the 2006 revision of the Long-term Care Insurance Act introduced preventive care services. At that point, recipients previously certified to receive Care Level 1 were split into Long-term Care Level 1 or Preventative Support Level 2 depending on whether their condition seemed likely to improve or remain the same.

<Column> The number of users at the time of the establishment of the Long-term Care Insurance System

Before establishing the Long-term Care Insurance System, care for the elderly was split between a system of welfare for the elderly and a system of healthcare for the elderly. To ensure that people who had been receiving welfare services could continue to use the same services in the new system, certification criteria were relaxed. This led to an immediate increase in the number of users requiring in-home care or light care (Preventative Support Level 1 / Long-term Care Level 1), thus creating bottlenecks and long-waiting lists at intensive care nursing homes. (Ikegami Naoki, 2017)

Figure 3-2-2: Yearly trend in number of people requiring care/support



Source: Created by HGPI and PwC based on data from the "2015 annual report on the state of the nursing-care insurance system" by the Ministry of Health, Labour and Welfare

⁶⁵ Ministry of Health, Labour and Welfare "The Long-term Care Insurance System" www.mhlw.go.jp/file/06-Seisakujouhou-12300000-Roukenkyoku/2gou_leaflet.pdf (accessed 21 September 2017)

3.3 The Health Insurance System | Private Health Insurance

Roles played by private health insurance under universal health coverage

Private health insurance mainly plays roles complementary to the public health insurance system such as guaranteeing services that are not covered by public benefits, guaranteeing additional expenses incurred during periods of illness, and guaranteeing income security during leaves of absence.^{66,67}

In addition, when taxpayers pay life insurance premiums, long-term care insurance premiums, or individual annuity insurance premiums, they can receive certain income-based deductions. These are called life insurance deductions, and they reduce the burdens of income tax and residence tax.

Background of rapid growth in the private health insurance sector

Insurance policies such as those for healthcare and cancer are classified as third-sector insurance policies (For additional information, please refer to the Glossary). Entry into the third-sector insurance industry was first permitted only to foreign life insurance companies in the early 1970s, but after drastic industry reforms in 1995 and the full liberalization of the third-sector insurance market in 2001, domestic companies were also allowed to sell insurance.⁶⁸ The number of in-force health insurance contracts in the third-sector has been consistently on the rise,⁶⁹ and such contracts have become the main life insurance product. In recent years, new product types such as special medical insurance (medical insurance with relaxed underwriting regulations) for "people with chronic illnesses and pre-existing conditions" have been developed for people who previously had difficulty joining private health insurance plans. Against this backdrop, the number of in-force contracts in the private health insurance sector has been increasing annually. In 2016, the number of medical insurance contracts that specifically covered services such as hospitalization and surgical security in their main life insurance sections had grown to 35.29 million.⁷⁰

Future expectations for the role of private health insurance

The current public health insurance system in Japan offers a wide range of benefits and is a Free Access system. The fact that private health insurance plays a limited role compared with other countries can also be explained by factors such as the High-cost Medical Expense Benefit System and the ban on mixed medical treatments. The need for private health insurance is gradually changing due to epidemiologic shifts, increasing demand for treatments of cancer, which is now the leading cause of death in Japan, and the expansion of advanced medical care services. As a result, the role of private health insurance is expected to transition in the future alongside reforms to the public health insurance system.^{71,72} Japan's declining birth rate, aging population, and technological innovations

⁶⁶ Tajika Eiji, Kikuchi Jun (2012) "The Role of Government and Private Insurance in Medical Security: A Theoretical Framework and Case Studies by Country" http://www.mof.go.jp/pri/publication/financial_review/fr_list6/r111/r111_02.pdf (accessed 21 November 2017)

⁶⁷ Nakahama Takashi (2006) "The Role of Private Medical Insurance—Through Comparison Between Japan and the United States" https://www.istage.ist.go.jp/article/isis/2007/596/2007_596_596_69/.pdf (accessed 21 November 2017)

⁶⁸ Serizawa Nobuko (2010) "Third-sector insurance market" http://dSPACE.lib.niigata-u.ac.jp/dSPACE/bitstream/10191/16657/1/90_249-271.pdf (accessed 21 November 2017)

⁶⁹ The Life Insurance Association of Japan "2017 Life Insurance Trends" <http://www.seiho.or.jp/data/statistics/trend/pdf/all.pdf> (accessed 21 November 2017)

⁷⁰ The Life Insurance Association of Japan "2017 Life Insurance Trends" <http://www.seiho.or.jp/data/statistics/trend/pdf/all.pdf> (accessed 21 November 2017)

⁷¹ Nakahama Takashi (2006) "The role of private health insurance -through comparison between Japan and the US- " https://www.istage.ist.go.jp/article/isis/2007/596/2007_596_596_69/.pdf (accessed 21 November 2017)

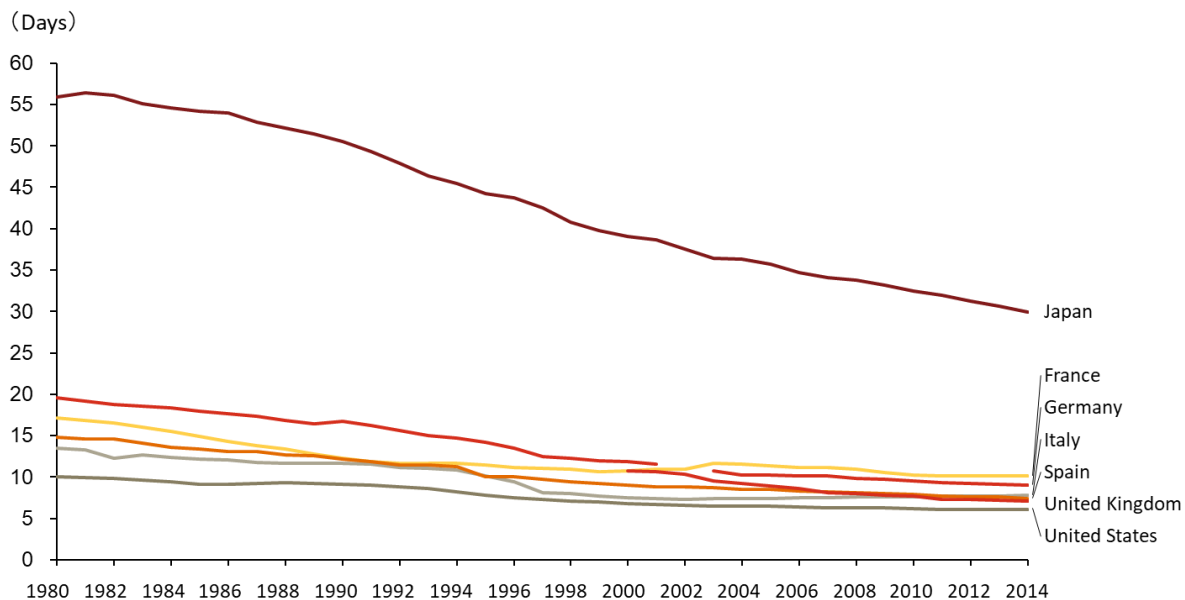
⁷² Kawaguchi Hiroyuki, "International Comparison of Public Medical Security System and Private Medical Insurance - Role Sharing of Public and Private Funding and Its Function -" Retrieved from <http://www.seijo.ac.jp/pdf/faeco/kenkyu/196/196-kawaguchi.pdf> (accessed 21 November 2017)

are also expected to raise national medical care expenditures, so revisions of public health insurance may result in reduced ranges of coverage. The private insurance plans currently offered in the market primarily cover limited services for fixed fees; however, it is predicted that in the future, these private plans will expand to cover medical services no longer covered publicly.

4.1 The Healthcare Delivery System | Overview of Japan's Healthcare Delivery System

Under universal health coverage (UHC), and because Japan's healthcare delivery system ensures unrestricted access, patients are able to receive care at any medical facility throughout the country. Another characteristic of Japan's healthcare delivery system is that it is primarily managed by private organizations, with private hospitals (medical corporations) accounting for 70% of all hospitals and owning 50% of all hospital beds. When viewed from an international perspective, the number of hospital beds per capita in Japan is comparatively high, the average length of hospitalization is long, and the number of healthcare professionals per bed is low. For example, as shown in Figure 4-1-1, although the average length of hospitalization is falling, it remains long in comparison to other countries. On the other hand, it is important to recognize that simple comparisons are not possible, since the types of hospital beds used for calculations vary by country.⁷³

Figure 4-1-1: Average length of hospital stay in days – International comparison



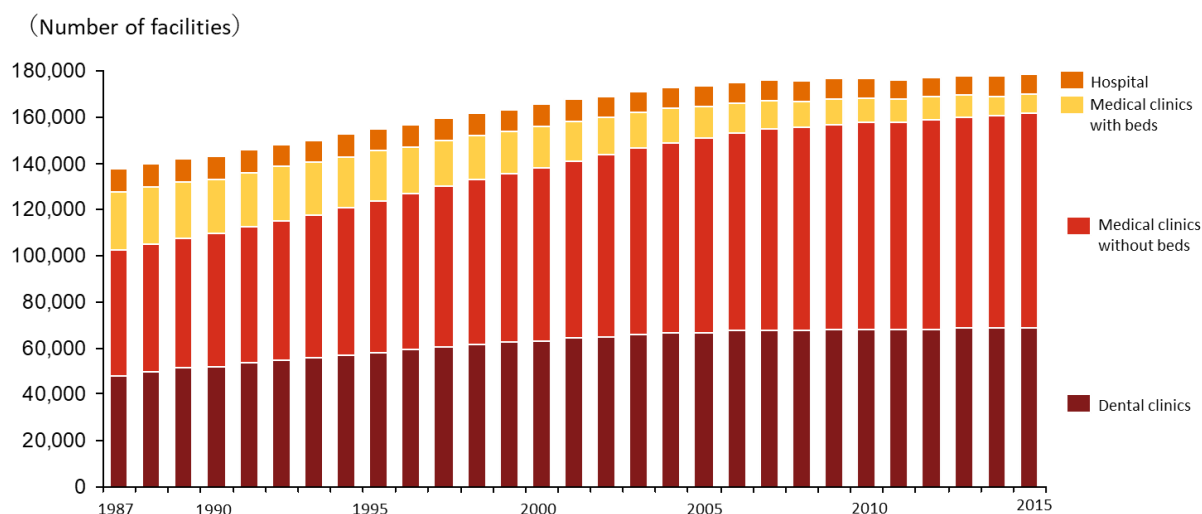
Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on "OECD-Health-Statistics-2017-Frequently-Requested-Data"

⁷³ Ministry of Health, Labour and Welfare "Current Situation and Issues Regarding the Healthcare Provision System" http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000184301.pdf (Accessed 2018, Feb.1)

4.2 Healthcare Delivery System | Classification of Medical Facilities and Hospital Beds in Japan

Medical facilities in Japan can be divided into medical clinics (inpatient/outpatient), dental clinics, and hospitals. As can also be seen from Figure 4-2-1, medical clinics account for most medical facilities.

Figure 4-2-1: Trend in number of medical facilities



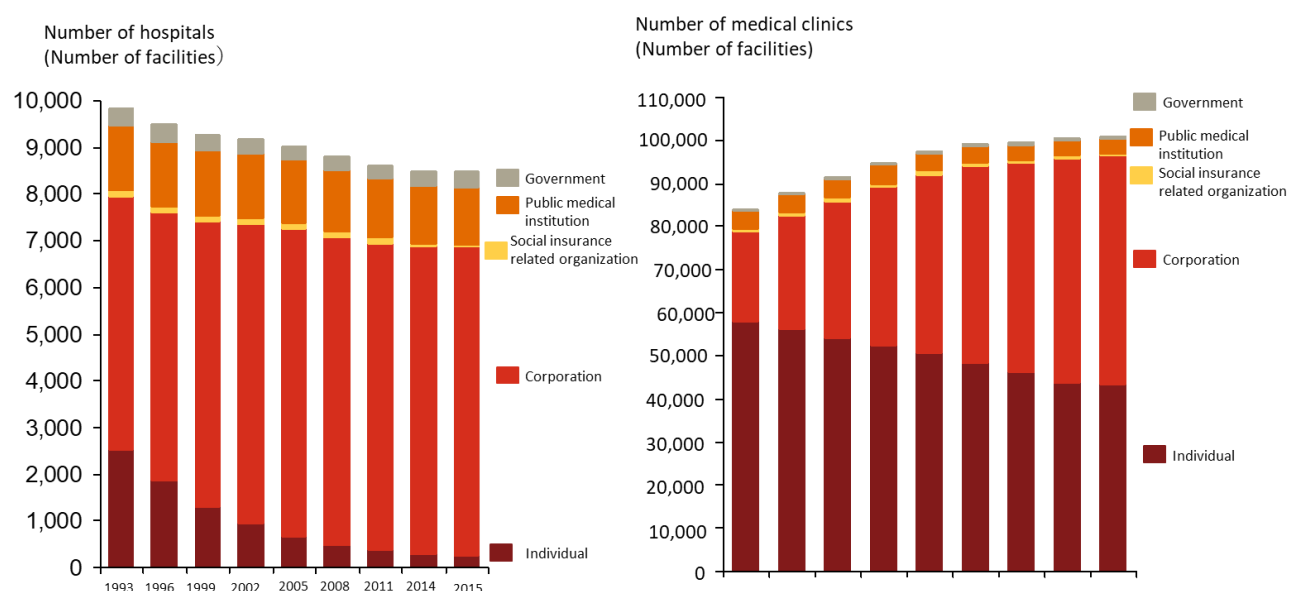
Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "2015 survey on medical facilities" available from the Ministry of Health, Labour and Welfare

Hospitals and medical clinics are distinguished in Japan based on their numbers of beds. Facilities with 20 or more beds are referred to as "hospitals," while facilities with 19 or fewer beds or lacking in-patient accommodations are referred to as "clinics." As of 2015, Japan had 8,480 hospitals, 7,961 in-patient medical clinics, 93,034 out-patient clinics, and 68,737 dental clinics. Looking at the changes in medical facilities from 1987 to 2015, the number of hospitals declined by a factor of 0.86, while the number of out-patient clinics grew by a factor of 1.7.⁷⁴

⁷⁴ Ministry of Health, Labour and Welfare "Survey of Medical Facilities" http://www.mhlw.go.jp/toukei/saikin/hw/iryosd/15/dl/02_01.pdf (Accessed 2017, Nov.20)

Hospitals and clinics can be broadly categorized by the organizations that manage them. There are national, public, social insurance organization, corporate, and private facilities, among others. As can also be seen from Figure 4-2-2, private hospitals continue to be the main healthcare provider within Japan's healthcare delivery system, but corporate clinics are gaining prominence. This characteristic of Japan's healthcare delivery system is unique, since the majority of hospitals in other countries such as the United Kingdom and France are public facilities.⁷⁵

Figure 4-2-2: Trend in number of medical clinics and hospitals per developer



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "2015 survey on medical facilities" available from the Ministry of Health, Labour and Welfare

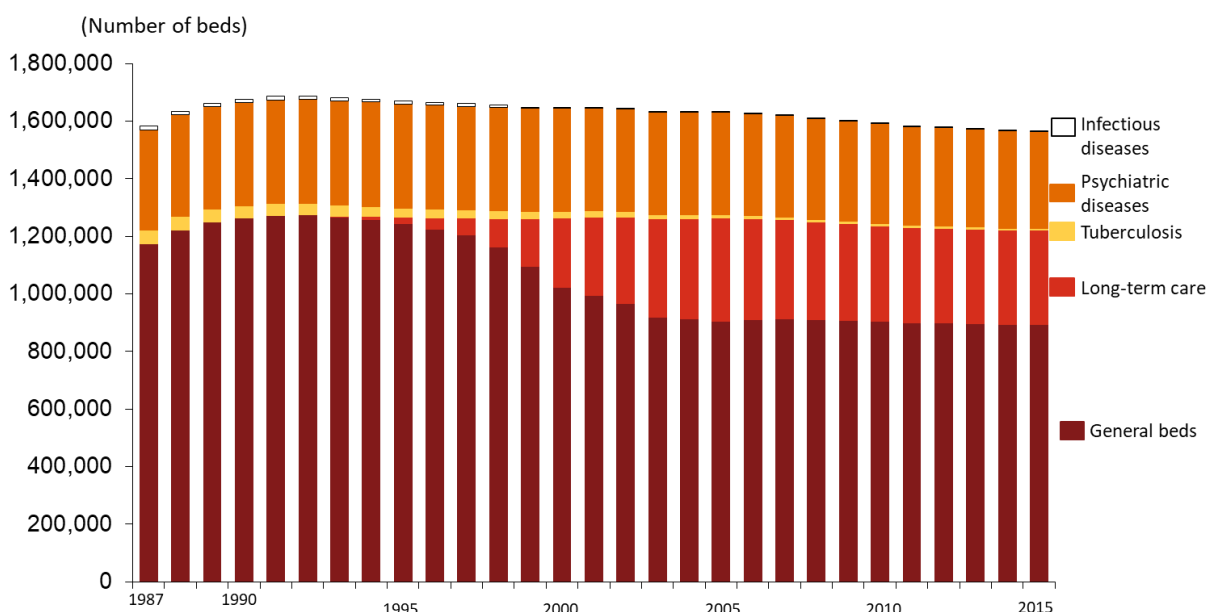
The types of hospitals operating in Japan include general hospitals, advanced treatment hospitals, regional support hospitals, clinical research hospitals, psychiatric hospitals, and tuberculosis hospitals. Among these, advanced treatment hospitals, regional support hospitals, and clinical research hospitals have requirements that vary from those of general hospitals regarding matters such as staffing. Only hospitals that fulfill these requirements may be licensed to operate.⁷⁶

⁷⁵ Ministry of Health, Labour and Welfare "Survey Research Regarding the Actual Situation of Medical Corporations Outside of Japan" http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/igyou/igyoukeiei/anteika.html (Accessed 2017, Nov.20)

⁷⁶ Ministry of Health, Labour and Welfare "Ministry of Health, Labour and Welfare 2015 Fiscal Year Edition White Papers " <http://www.mhlw.go.jp/wp/hakusyo/kousei/17-2/dl/02.pdf> (Accessed 2017, Nov.27)

Hospital beds in Japan are classified as general beds, long-term care beds, psychiatric beds, infectious disease beds, and tuberculosis beds⁷⁷. Although prior to the 4th revision of the Medical Care Act in 2000, “long-term care beds” and “general beds” were combined in a single category referred to as “other beds,” this category was split to facilitate more circumstance-appropriate healthcare delivery. As can be seen in Figure 4-2-3, most hospital beds are general beds.

Figure 4-2-3: Trend in number of hospital beds per bed type



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the “2015 survey on medical facilities” available from the Ministry of Health, Labour and Welfare

In terms of general hospital bed trends, due to healthcare expense burden mitigation measures implemented after the achievement of universal health coverage such as the High-Cost Medical Expense Benefit System, public demand for medical care increased, and in accordance, the numbers of hospitals and hospital beds increased as well. It is also worth noting the reality that general hospital bed numbers are propped up by many “socially hospitalized” patients who are unable to leave hospitals and return home due to financial hardships or other reasons.⁷⁸

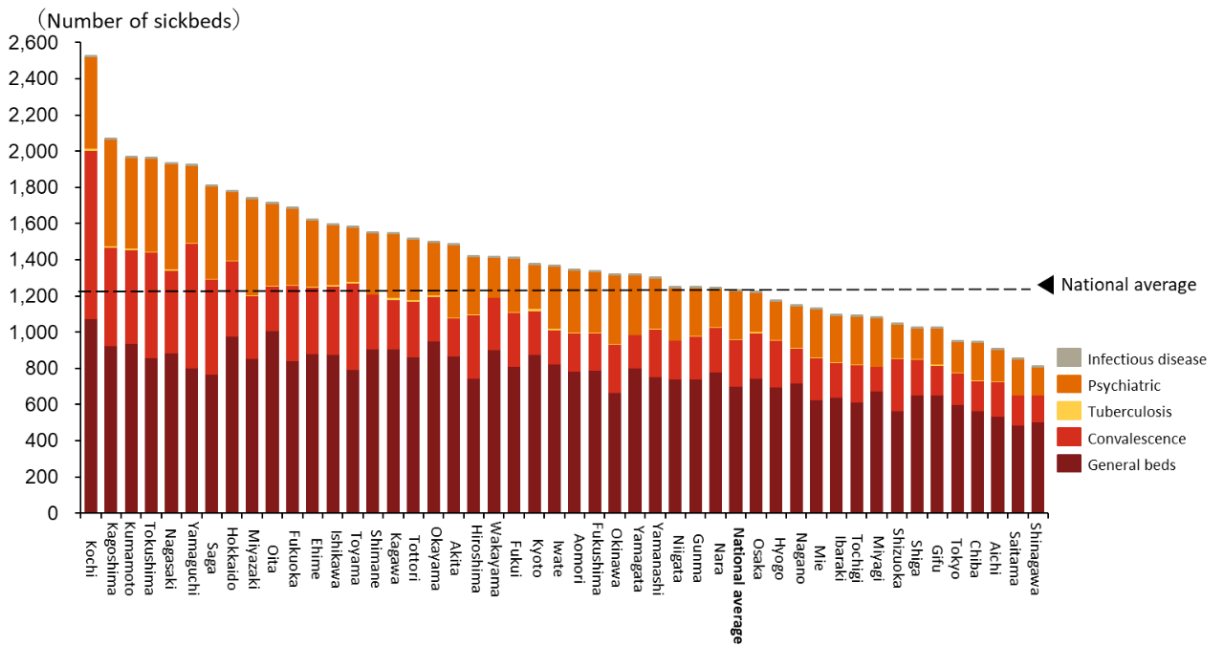
By 2025, all members of the Baby Boomer generation (those born between 1947 and 1949), will reach age 75 or over, inducing sharp increases in social security costs, including long-term care expenditures and medical care expenditures. With the aging of the Japanese population predicted to progress even more rapidly in the future, it is important for Japan to effectively utilize its limited medical resources. To ensure patients are able to access appropriate care at the appropriate facility regardless of their location or situation, the government is functionally differentiating medical facility beds according to needs, aiming to reduce the number of hospital beds to between 1.15 and 1.19 million by 2025.

⁷⁷ Ministry of Health, Labour and Welfare “Ministry of Health, Labour and Welfare 2015 Fiscal Year Edition White Papers ” <http://www.mhlw.go.jp/wp/hakusyo/kousei/17-2/dl/02.pdf> (Accessed 2017, Nov.27)

⁷⁸ National Federation of Health Insurance Societies (2017) *Healthcare Coverage Seen Through Charts, 2017 Edition*, Gyosei Corporation, p.43

As shown in Figure 4-2-4, there are large disparities among prefectures in terms of the number of hospital beds. The number of hospital beds per 100,000 people is about three times higher in Kochi Prefecture, where it is the highest, than in Kanagawa Prefecture, where it is the lowest. In efforts to realize a more ideal future healthcare delivery system, Japan is addressing such regional disparities by formulating Regional Medical Care Visions (See Section 4.4) and reporting hospital bed functions and needs to prefectural governors.

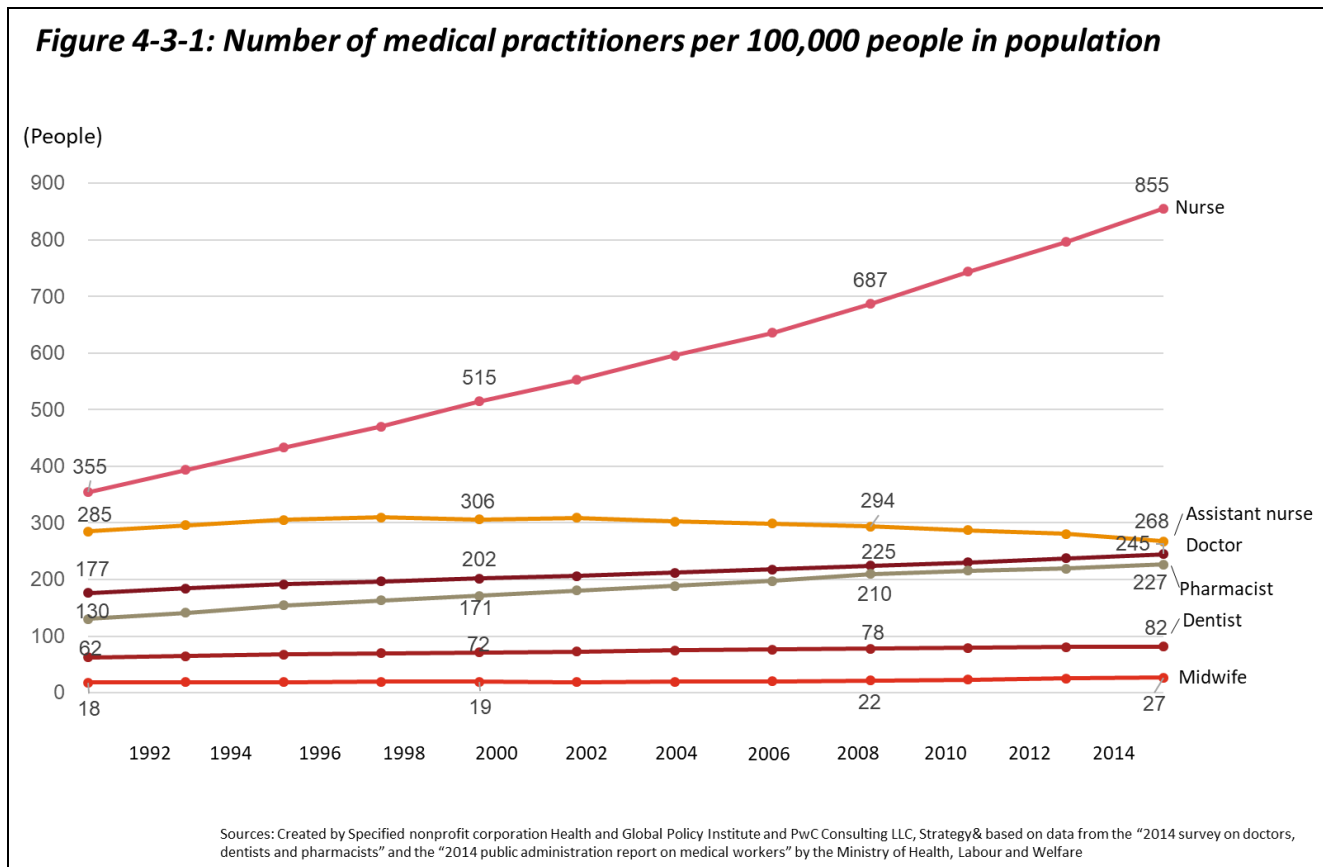
Figure 4-2-4: Number of beds per 100,000 people in population, by prefecture and bed type (1 October 2015)



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "2015 survey on medical facilities" available from the Ministry of Health, Labour and Welfare

4.3 The Healthcare Delivery System | Numbers of Medical Professionals

As shown in Figure 4-3-1, nurses are the fastest-growing category among medical professionals in Japan, while the number of doctors has remained relatively constant, only increasing by about 4,000 people per year.



Although doctor shortages previously pointed out in obstetrics and general surgery have been in decline since 1994, regional maldistribution of doctors remains an issue, so a variety of actions are being undertaken. Specific examples include (1) supporting increases in university admissions by utilizing regional frameworks; (2) supporting regional medical support centers; (3) supporting clinical departments that suffer from shortages such as obstetrics and pediatrics; (4) supporting clinical training programs, (5) supporting a new system of medical specialists; and (6) organizing conferences to discuss the demands of medical practitioners. Regarding point (5), although implementation of the new medical specialist system was originally planned for FY2017, it was postponed until FY2018 due to concerns that the system might cause significant confusion in regional medical institutions.⁷⁹

Concerning the new medical specialists system, which has been the subject of much debate related to the impact that it will have on regional healthcare in terms of the maldistribution of physicians, many have thus far expressed concerns about the consistency of accreditation standards for specialists under the independently managed academic institutions and the maintenance of physician quality. The new system has been constructed with the aim of improving that quality and providing high-quality medical care. Specifically, a framework has been

⁷⁹ Ministry of Health, Labour and Welfare "2. Physician Maldistribution Countermeasures" http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000184302.pdf (Accessed 2018, Feb.1)

established for appointing neutral, third-party organizations and for the consistent evaluation and certification of specialist accreditation and specialist development programs.⁸⁰

⁸⁰ Ministry of Health, Labour and Welfare "2. Physician Maldistribution Countermeasures" http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000184302.pdf (Accessed 2018, Feb.1)

4.4 The Healthcare Delivery System | Regional Medical Care Delivery System Maintenance

Regional governments are also launching various measures in response to the issues of the medical delivery system. Along with establishing efficient, high-quality regional healthcare delivery systems, via the creation of regionally comprehensive systems and by enforcing the Acts for Securing Comprehensive Medical and Long-Term Care in the Community (intended to promote the comprehensive maintenance of medical and long-term care systems in each region), governments are taking major actions to establish Regional Medical Care Visions within their Medical Care Plans (MCPs) and to construct regionally comprehensive care systems. The sections below highlight specific actions.⁸¹

Medical Care Plans

The obligation to create Medical Care Plans (MCPs) was established in the 1985 revision of the Medical Care Act, with the objective of promoting regional healthcare delivery systems by encouraging the efficient use of medical resources. Regional governments formulate MCPs based on the actual regional circumstances they face as they work to maintain their healthcare delivery systems. MCPs include measures for the management of hospital bed numbers and the maintenance of systems needed to provide high-quality healthcare.

Each MCP must address points such as the following: (1) five diseases (cancer, stroke, acute myocardial infarction, diabetes mellitus, and psychiatric disorders); (2) five project areas (emergency care, care in the case of a disaster, care in remote areas, perinatal care, and pediatric/emergency pediatric care); (3) goals to be achieved for in-home care; (4) medical collaboration systems; (5) securing of human resources in the healthcare field; (6) promotion of information provision to the public; (7) ensuring safety in the healthcare field; (8) promotion of secondary and tertiary healthcare; and (9) standardization of calculations for general hospital bed numbers.

Regional governments typically review their MCPs in accordance with revisions to the Medical Care Act. Following the sixth revision of the Medical Care Act in 2014, in order to "formulate regionally comprehensive care systems along with efficient, high-quality healthcare delivery systems," regional governments have been working to comprehensively ensure medical and long-term care, to establish hospital bed function reporting systems, to formulate regional care plans, and to establish Regional Medical Care Vision Councils.⁸²

Regional Medical Care Visions

Medical and long-term care expenses are predicted to increase rapidly in 2025, when the Baby Boomers reach the ages of 75 years or over. Growth in the elderly population varies by region, so in order to effectively and efficiently distribute healthcare resources commensurate with each region's functional needs, and based on the recognition that it is crucial each region maintain a healthcare system that can provide high-quality healthcare services in line with the circumstances of patients—whether they require acute, recovery, or chronic care—it was decided that each region should establish a "Regional Medical Care Vision" within its Medical Care Plan.

The Medical Care Act, revised in accordance with the Acts for Securing Comprehensive Medical and Long-Term Care in the Community, stipulated the establishment of plans (regional MCPs) aimed at ensuring the future of medical delivery systems. Those plans must set out Regional Medical Care Visions that include the matters

⁸¹ Ministry of Health, Labour and Welfare "Promotion of Comprehensive Long-term and Medical Care Act" http://www.mhlw.go.jp/file/06-Seisakujouhou-12600000-Seisakutoukatsukan/0000038005_1_2.pdf (Accessed 2018, Feb.2)

⁸² Ministry of Health, Labour and Welfare "Regional Inclusive Care System" http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/hukushi_kaigo/kaigo_koureisha/chiiki-houkatsu (Accessed 2017, Oct.20)

specified via an MHLW ordinance such as standards for promoting the functional differentiation of hospital beds and regional collaboration. Prefectural governments must establish Regional Medical Care Visions that consider the future necessity of each medical function per vision category by making use of estimates of future regional demands and reported information. Governments must incorporate this information into their MCPs. This process helps to further promote functional differentiation across medical institutions.

Regional Medical Care Visions include the 2025 healthcare demands (categorized by inpatient/outpatient, disease, etc.), the ideal healthcare delivery system that the region aims to create by 2025 (extent of necessity for medical facilities in each secondary health management area etc.), and the measures/policies necessary for realizing these systems.

Other Major Policies

The Comprehensive Strategy to Accelerate Dementia Measures (The New Orange Plan)⁸³

Aging of the population has turned dementia into one of Japan's major issues. By 2025, roughly 7 million people will be living with dementia. Currently, 1 in 5 people aged 65 or over live with dementia in Japan, but by 2025 that number will rise to 1 in 7. In such a society, it will be important to think beyond merely supporting those with dementia and also focus on how to help them live better lives. To that end, MHLW has been seeking a wide array of opinions from various stakeholders, including people living with dementia and their families. Based on those opinions and in cooperation with other related ministries and agencies, the MHLW formulated the "New Orange Plan."

Overview of New Orange Plan Goals

- Promote understanding and raise awareness about dementia (E.g. run awareness-raising campaigns and trainings for dementia supporters)
- Provide appropriate medical and long-term care according to the stage of the disease (E.g. provide thorough, patient-centered medical and long-term care, encourage people to take measures to prevent the onset of dementia, and develop systems for early diagnosis and treatment)
- Strengthen early-onset dementia policies (E.g. raise and spread awareness)
- Support caregivers for people living with dementia (E.g. create early-stage dementia Integrated Support Teams (IST) involved in early diagnosis and treatment)
- Promote the creation of aging- and dementia-friendly communities (E.g. enact abstract initiatives such as for livelihood support as well as concrete initiatives such as for the creation of easily livable environments)
- Promote R&D and the dissemination of results on topics such as dementia prevention methods, diagnostic methods, treatment methods, rehabilitation techniques, and long-term care models (E.g. clarify the pathophysiology of dementia)
- Emphasize viewpoints of people living with dementia and their families (E.g. grasp the needs of those in the early stages of dementia and support their quality of life)

Cancer Countermeasures⁸⁴

In Japan, cancer has been the leading cause of death since 1981. In 2015 alone, 370,000 people died from cancer. In light of this situation and with the objective of further enhancing cancer countermeasures, the Cancer Control Act was established in June 2006, and enforced in April 2007. In June of 2007, in order to comprehensively and systematically promote cancer countermeasures, Phase One of the Basic Plan to Promote Cancer Control Programs was formulated.

The First Term of the Basic Plan (FY2007 - FY2011) laid out the establishment of "Designated Cancer Care Hospitals," the strengthening of palliative care delivery systems, and the improvement of regional cancer registries.

⁸³ Ministry of Health, Labour and Welfare "Comprehensive Strategy for the Promotion of Dementia Measures (New Orange Plan)" <http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000064084.html> (Accessed 2018, Mar.2)

⁸⁴ Ministry of Health, Labour and Welfare "Basic Plan for Promoting Cancer Countermeasures" <http://www.mhlw.go.jp/file/04-Houdouhappyou-10901000-Kenkoukyoku-Soumuka/0000181862.pdf> (Accessed 2018, Mar.2)

The Second Term of the Basic Plan (FY2012 - FY2016) tackled such issues as pediatric cancer, cancer education, and cancer patient employment. To add to that, in December of 2015, the "Plan to Accelerate Cancer Control Programs" was formulated.

Although a variety of efforts were made via such cancer countermeasures, Japan was unable to achieve its 10-year goal set in FY2007 of "decreasing the age-adjusted cancer mortality rate by 20% (for those under 75 years of age)." In light of the situation, Japan needs to strengthen preventive policies even further from here on out. It is also important to increase the rate of screenings for the early detection and treatment of cancers.

The overall goal for the Third Term of the Basic Plan to Promote Cancer Control Programs (FY2017 - FY2022) states that "The Japanese public, including cancer patients, will aim to understand and overcome cancer." A categorized outline of the policies of this Term is shown below.

- Cancer prevention

(1) Primary prevention of cancer; (2) Cancer screenings and early detection (secondary prevention)

- Improvement of Cancer Treatments

(1) Genomic medicine; (2) Surgical therapy, radiation therapy, chemotherapy, and immunotherapy; (3) Team care; (4) Rehabilitation; (5) Psychological and emotional support; (6) Rare and treatment-resistant cancer (measures according to the characteristics of each cancer); (7) Childhood cancer, AYA (Adolescent and Young Adult) cancer, and cancer in the elderly; (8) Pathological diagnosis; (9) Cancer registration; (10) Efforts aimed at early development and approval of pharmaceuticals and medical devices

- Living with cancer

(1) Palliative care from the time of diagnosis; (2) Counseling and support, communication of information; (3) Countermeasures/support based on community cooperation; (4) Social issues including the employment of cancer patients; (5) Countermeasure that correspond to developmental life stages. Cancer research, human resource development, cancer education, and raising public awareness make up the foundation that supports these three pillars.

The following points are also listed as necessary for the comprehensive and systematic promotion of cancer countermeasures: further strengthening of collaboration and cooperation among stakeholders; formulation of plans by prefectural governments; efforts by the public, including cancer patients; cooperation with patient organizations; implementation of necessary fiscal measures and budget optimization/prioritization; progress assessments and reviews of the Basic Plan.

5.1 Medical Cost Optimization Measures | Medical Cost Optimization Plans

Japan is implementing a variety of cost-optimizing measures in order to suppress excessive increases in medical costs. Among them are Medical Cost Optimization Plans, which set out general targets and medical cost estimation methodology. In line with the targets and methods indicated in the National Medical Cost Optimization Basic Policies, each prefectural government must also prepare its own Medical Cost Optimization Plan.⁸⁵

The initial National Plan was executed in two phases. The first phase spanned FY2008 to FY2012 and the second, FY2013 to FY2017. The goals of these five-year phases were to "reduce the length of average hospital stays" and to "improve the implementation rates of Specific Medical Examinations." A third phase was created following the completion of the second, slated to last from FY2018 to FY2023. With optimization as the stated goal, this six-year phase will continue to promote efforts to improve the implementation rates of Specific Health Examinations, while newly including "efforts to prevent the worsening of diabetes," "promotion of the use of generic drugs," and "the appropriate use of pharmaceuticals (including issues related to redundant prescriptions and concomitant use)." The new phase also takes into account hospitalization cost estimates based on the results of promoting functional differentiation of hospital beds.

The Concrete Direction of the National Medical Cost Optimization Basic Policies from 2018 Onwards

At the end of FY2017, a Ministerial Notice was issued on the Basic Policies for Medical Cost Optimization. In terms of a concrete direction for these policies, the notice discussed the calculation formulas used by prefectures to estimate medical cost targets (outpatient expenses and inpatient expenses) as well as efforts taken by prefectures to promote the optimization of medical costs (numerical target-setting when possible). Specific issues discussed in that notice are listed below:

- Outpatient Medical Expenses

Prefectural medical cost targets are to be set based on historical trends. From FY2023 these targets will reflect the effects of medical cost optimization efforts. These effects will be reviewed in two stages. In the first stage, Japan will review medical cost reductions achieved via efforts to meet national targets for Specific Health Examinations and Specific Health Guidance implementation rates as well as targets for the use of generic drugs. In the second stage, Japan will work to reduce regional disparities in medical costs per capita by strengthening incentive measures for health-promotion such as the implementation of point-based healthcare systems and also by promoting efforts to reduce redundant prescriptions.

- Inpatient Medical Expenses

Japan will estimate inpatient expenses based on the outcomes of efforts to differentiate hospital beds by function and promote collaboration among medical facilities. Regarding the functional differentiation of hospital beds, Japan will work to shorten the amount of time that patients spend in advanced-acute and acute beds and lengthen the amount of time spent in recovery beds. In terms of regional disparities among inpatient expenses, because a strong correlation exists between hospitalization costs and the numbers of beds in each region, prefectural governments are being asked to formulate Medical Cost Optimization Plans consistent with their Regional Medical Care Visions. Ultimately, Japan will aim to cut hospitalization costs in half.

⁸⁵ Ministry of Health, Labour and Welfare "Revision of Basic Policies for Medical Cost Optimization / Plans for Medical Cost Optimization" <http://www.mhlw.go.jp/file/05-Shingikai-12401000-Hokenkyoku-Soumuka/0000148008.pdf> (Accessed 2017, Nov.27)

- Visualizing Regional Disparities

The National Government will conduct data analyses using Japan's National Database (NDB) to bring into view prefectural disparities among medical costs, generic drug usage, and redundant prescriptions / concomitant drug usage. Summarized results from these analyses will be provided as datasets to prefectural governments as reference material for analyses.

5.2 Medical Cost Optimization Measures | Disease Prevention and Health Promotion by Insurers

The Health Science Council's Community Health and Nutrition Team released an interim report on September 15, 2005, entitled "Future Promotion of Lifestyle Disease Countermeasures." That report cited challenges such as the following regarding the promotion of lifestyle disease countermeasures: insufficient sampling reliability of populations at risk for lifestyle diseases and insufficiently thorough health guidance; the need for thorough, evidence-based health examinations and guidance; the need for further improvements in the quality of health examinations and guidance; insufficient presentation of concrete strategies and programs by the National Government; and insufficient general understanding of the current situation / insufficient data for policy evaluations. The creation and strengthening of lifestyle disease countermeasures was deemed necessary in order to address these issues.⁸⁶ To that end, "Specific Health Examinations" and "Specific Health Guidance" were formulated in April 2008. Furthermore, in order to successfully "extend the nation's healthy life expectancy," (an important measure within the Japan Revitalization Strategy), it was decided that health insurance associations would be required to draw up and implement Data Health Plans and that corporations would be required to promote corporate wellness efforts.⁸⁷

Specific Health Examinations / Specific Health Guidance

The Japanese government has formulated treatment plans for medical practitioners—Specific Health Examinations and Specific Health Guidance—in an effort to tackle lifestyle diseases, which are causal factors in approximately 60% of deaths each year in Japan. Specific Health Examinations and Specific Health Guidance focus on treating metabolic syndrome in adults ages 40 to 74. This is done through a two-step process. Patients first receive Specific Health Examinations. For patients identified as being at high risk for developing lifestyle diseases and who can expect preventative effects from lifestyle changes, public health nurses then provide Specific Health Guidance, supporting the re-examination of lifestyle choices. The MHLW created this program with the goal of reducing the number of people suffering from lifestyle diseases such as diabetes by 25% between FY2008 and FY2017. Based on that goal, individual insurers are expected to create plans to promote Specific Health Examinations and Specific Health Guidance for enrollees. These plans are created based on basic measures laid out by the national government such as Specific Health Examinations.

At present, the actual implementation rate for Specific Examinations among all insurers is 50.1%. When broken down by insurer type, implementation rates vary considerably, with municipal sections of the NHI at 36.3%, the National Health Insurance Association at 46.7%, the Japan Health Insurance Association at 45.6%, National Seamen's Insurance at 46.8%, Health Insurance Societies at 73.9%, and Mutual Aid Associations at 75.8%. Although rates for Health Insurance Societies and Mutual Aid Associations exceed 70%, rates remain low for other insurers, such as municipal sections of the NHI. Implementation rates for Specific Health Guidance, when compared to rates for Specific Health Examinations, are significantly low for every single insurer, with municipal sections of the NHI at 23.6%, the National Health Insurance Association at 8.9%, the Japan Health Insurance Association at 12.6%, National Seamen's Insurance at 6.9%, Health Insurance Societies at 18.2%, and Mutual Aid Associations at 19.6%.⁸⁸

⁸⁶ Ministry of Health, Labour and Welfare "Future Promotion of Lifestyle Disease Countermeasures (Interim Summary)" <http://www.mhlw.go.jp/shingi/2005/09/s0915-8.htm> (Accessed 2017, Nov.21)

⁸⁷ Ministry of Health, Labour and Welfare "Section 1: Background and Aims of the Data Health Plan" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000069365.pdf> (Accessed 2018, Feb.7)

⁸⁸ Ministry of Health, Labour and Welfare "2015 Fiscal Year Implementation Status of Specific Health Examinations and Specific Health Guidance" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000173319.pdf> (Accessed 2018, Feb.2)

One reason for low Specific Health Guidance implementation rates is that same-day blood test results are unavailable, so it can take several months from screening to guidance.⁸⁹

Data Health Plans

In response to the development of advanced population aging and following Japan's monetary and fiscal policies as the "Third Arrow" of Abenomics, the Japan Revitalization Strategy was announced, setting "extension of the nation's healthy life expectancy" as an important goal. During the first phase of this initiative, between FY2015 and FY2017, in order to realize that goal and as a new approach for disease prevention and health promotion, all health insurers were required to prepare and publish Data Health Plans. These plans laid out strategies that each insurer would take to maintain and improve the health of its enrollees based on analyses of health and claims data. As of April 2018, the second phase of Data Health Plans was implemented and is now headed for full-scale implementation. Similar initiatives are also required for the municipal sections of NHI. By preparing and utilizing Data Health Plans, it is hoped that health insurers will move toward the operation of more effective healthcare programs.

One goal for the creation of Data Health Plans is to promote the effective and efficient implementation healthcare programs via plan-do-check-act (PDCA) cycles based on analyses of health and claims data. Another goal is the realization of healthy workplaces through collaborative health programs in which businesses cooperate with insurers on initiatives to create healthy working environments and improve the health awareness and lifestyle habits of employees.⁹⁰ This goal is clarified within the Basic Policies on Economic and Fiscal Management and Reform 2016 ("Big-Boned Policies") approved by a Cabinet order in 2016 which states that "Further collaboration between corporate wellness and data health measures will be promoted by corporations." There are high hopes for preventative medicine and health promotion measures implemented by insurers.

Corporate Wellness

Corporate wellness is the act of thinking about employee healthcare from an administrative perspective and undertaking strategic actions. It has been pointed out that increasing national medical costs will further worsen the fiscal situations of insurance associations and other insurers. This will lead to increases in insurance premiums, in turn requiring increased contributions from insured individuals and corporations. In addition, as the working-age population shrinks in concert with continual birthrate decline and ageing of the population, there is concern that the overall health of the working population will suffer, reducing the abilities of companies in Japan to secure human resources and leading to overall decreases in corporate productivity. For corporations, the maintenance and improvement of employee health combined with optimization of medical costs and improvements in productivity can all be considered investments in the future.⁹¹

In addition, the promotion of employee health can improve a corporation's public image, increase productivity, contribute to organizational revitalization, and improve corporate performance. The Ministry of Economy, Trade and Industry (METI) has selected corporations that are strategically engaging with corporate wellness, recognizing one company in each industry as a "Corporate Wellness Brand." Through this initiative, the government is building the social capital of companies and encouraging them to further promote corporate wellness.

In July of 2017, MHLW published the "Collaborative Health Guidelines for the Promotion of Data Health and Corporate Wellness." These guidelines summarize the significance of collaborative health efforts, and offer

⁸⁹ Ministry of Health, Labour and Welfare "Future Measures for Increasing the Implementation Rates of Specific Health Examinations and Specific Health Guidance" <http://www.mhlw.go.jp/stf/shingi/2r9852000002e0cn-att/2r9852000002e0hh.pdf> (Accessed 2018, Feb.2)

⁹⁰ Ministry of Health, Labour and Welfare "Primer on the Creation of Data Health Plans" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000178352.pdf> (Accessed 2018, Feb.2)

⁹¹ Ministry of Health, Labour and Welfare "The Corporate 'Workplace Wellness' Guidebook ~ Recommendations for Promoting Health Through Collaboration and Cooperation ~ (Rev.1st ed.)" http://www.meti.go.jp/policy/mono_info_service/healthcare/kenkokeiei-guidebook2804.pdf (Accessed 2018, Feb.9)

practical examples for both business owners and insurers such as health insurance associations on what efforts may be effective for promoting employee health, advancing business-insurer collaborations, and putting corporate wellness techniques into practice. In other words, these guidelines aim to make "Data Health" implemented by insurers such as health insurance associations and "Corporate Wellness" implemented by business owner, function more effectively when utilized in combination.⁹²

The Promotion of Incentives for Individuals and Insurers

The strengthening of incentives for individuals and insurers is yet another way to encourage preventative medicine and health promotion.

As an incentive for encouraging preventative medicine practices and health promotion in individuals, some insurers in Japan are implementing "healthcare points" systems or offering support such as for insurance payments. For example, enrollees who make the effort to receive Specific Health Examinations or who improve their examination results might receive health-related goods or discount coupons for future examinations.⁹³

In terms of strengthening incentives for insurers in order to make it easier, among other things, for them to fully apply their functions according to their unique characteristics, the following measures were included within policy revisions such as that of the National Health Insurance Act of 2015: (1) the establishment of insurer effort support systems for residence-based NHI, and the evaluation of objective indices and creation of subsidies for initiatives such as those aimed at preventing the worsening of diabetes; and (2) comprehensive reviews (implemented from FY2018) of the systems used for calculating financial support for people aged 75 and over who are enrolled in health insurance or mutual aid associations that evaluate insurers based on not only their reported results from Specific Health Examinations or Specific Health Guidance, but also on multiple other indices such as cancer treatment initiatives or collaborations with businesses. Reforms of the system for calculating contributions from health insurance associations and mutual aid associations for those aged 75 and over were implemented from FY2018, emphasizing incentives for insurers' efforts such as those aimed at disease prevention and health promotion. The reforms are expected to have far-reaching but minor implications in terms of penalties for many insurers, while introducing step-wise reductions in insurers' financial contributions according to their level of achievement on certain indices.

⁹² Ministry of Health, Labour and Welfare "Data Health and Collaborative Health Guidelines for Promotion of Corporate Wellness"
<http://www.mhlw.go.jp/stf/houdou/0000170819.html> (Accessed 2018, Feb.9)

⁹³ Ministry of Health, Labour and Welfare「Insurer Incentives」http://www.mhlw.go.jp/file/05-Shingikai-12601000-Seisakutoukatsukan-Sanjikanshitsu_Shakaihoshoutantou/0000163331.pdf (Accessed 2018, Nov.28)

6.1 Medical Drugs/Medical Devices | Pharmaceuticals

Definition of New Drugs

New Drugs (Originator drugs) are medical drugs which are clearly differentiated in active ingredients, dosage, administration, indication and efficacy from drugs which have already been approved. New Drugs mainly consist of drugs containing new active ingredients, new ethical combination drugs, drugs with a new administration route, drugs with a new indication, drugs in new dosage forms, and new dosage drugs.

Pharmaceutical Product Approvals

To manufacture, distribute and sell new drugs, pharmaceutical companies must first obtain marketing approval from the PMDA. Approvals are made by the PMDA based on an evaluation of the new drug's efficacy and safety information obtained via clinical trials. Clinical trial information and filing documents must conform to the quality, GLP and GCP requirements defined by the MHLW.

In addition to the standard approval process, the MHLW has implemented mechanisms for expedited reviews and approvals of innovative pharmaceutical products.

To address the development lag between Japan and other major markets, the MHLW implemented the "Sakigake" review policy in 2014 that awards prioritized reviews and expedited approvals for products that are developed for and filed for first in Japan. To be eligible for "Sakigake" reviews, new drugs must meet all of the following criteria: 1) innovative new mechanism of action, 2) degree of severity of the target indication, 3) high degree of effectiveness, and 4) a desire to develop and file first in Japan.

Furthermore, In 2017, the MHLW implemented the "Conditional Expedited Approval" Policy for drugs that address disease states with small patient populations with limited treatment options and large unmet medical needs for which the execution of confirmatory clinical trials are difficult. The policy enables pharmaceutical companies to file for approval with efficacy and safety data generated from non-confirmatory trials, such as phase II trials, on the condition that additional safety and surveillance measures, including the use of real world data, are implemented. It is expected that this policy will support the development of novel treatments including iPS cell based genetic therapies.

Pharmaceutical Reimbursement Pricing

Once marketing approval is obtained, manufacturers must apply for reimbursement pricing under the National Health Insurance (NHI) system. The NHI reimbursement price is the price at which payors reimburse medical institutions for pharmaceutical products used to treat patients.

Initial NHI Reimbursement prices that are set by the MHLW's Central Medical Council based primarily on the comparable based method when similar approved products already exist on the market, or the cost based method for novel therapeutics with no similar approved products.

In addition, the MHLW has also implemented pricing premiums to both incentivize the development of innovative products while constraining the reimbursement prices of products whose degree innovativeness are assessed to be limited. Products with superior efficacy or usefulness compared to existing products, with orphan or pediatric indications, or for which Japan is the first country are eligible for additional price premiums, whether priced via the comparator or the cost based methods

Once set, pharmaceutical reimbursement prices are revised biannually based on an assessment of the variance between NHI reimbursement prices and actual market (wholesale) prices. While the price difference between NHI reimbursement prices and actual market prices enable medical institutions and pharmacies to book revenue, biannual price revisions are intended to limit discounting to within a reasonable range known as the "R-zone" established by the MHLW, currently set at 2% of reimbursement prices. In practice, the biannual price revisions

have the effect of lowering drug prices, enabling the MHLW to control the natural growth in overall healthcare spending.

In addition to the standard biennial reassessment of drug prices in Japan, additional adjustments have also been implement to ensure products are profitable and to promote the development of new drugs while limiting overall costs by reducing prices for drugs that have seen significant market expansion or that have lost patent protection.

| Adjustment | Type | Description |
|---|---------------------|--|
| Lack of profitability | Positive adjustment | <ul style="list-style-type: none"> Unprofitable drugs with high medical need are eligible for an increase in NHI list price by MHLW or generics where all generic products are unprofitable |
| Market size expansion | Negative adjustment | <ul style="list-style-type: none"> Added price cuts for increased market size or sales due to indication expansion |
| Premium to promote the development of new drugs and eliminate off-label use | Positive adjustment | <ul style="list-style-type: none"> Premiums for innovative products designed to slow price reductions and promote new drug development |
| Additional Cuts for Long Listed Drugs | Negative adjustment | <ul style="list-style-type: none"> Additional cuts to long listed products Used to fund premiums for new drug development |

As healthcare costs continue to rise, it is expected that additional revisions to pharmaceutical reimbursement pricing mechanism may be made going forward. While undetermined, to date, topics such as the introduction of health economics outcome considerations when setting reimbursement prices in addition to potential shift towards annual price revisions have been discussed.

Pharmaceutical Product Quality and Safety

Similar to other major markets, the development, manufacture and distribution of pharmaceutical products in Japan are also governed by GXP regulations such as GLP, GCP, GMP and GVP standards. However, there are a few notable differences in Japanese regulations and policies related to product quality and safety.

First, under the Pharmaceutical Affairs Law, to comply with Japan's Good Quality Practices (GQP) and GVP requirements, pharmaceutical companies must designate three individuals to take on the following roles unique to Japan to oversee and govern product quality and safety related activities:

- General marketing compliance officer – Individual with overall responsibility for product quality and safety
- Quality assurance manager – Individual responsible to ensure quality activities comply with GQP regulations
- Safety manager – Individual responsible for ensure safety activities comply with GVP regulations

Second, upon approval of novel drugs, Japan requires pharmaceutical companies to conduct post marketing surveillance activities to track and ensure patient safety. Surveillance activities are generally required to be conducted during the 6 month period after launch and are intended to identify track any adverse events in the real world setting that may not have been observed during clinical trials. These activities are governed by Japan's Good Post-marketing Surveillance Practice (GPSP) regulations.

Third, to further ensure patient safety, new pharmaceutical products are generally restricted to 14 day prescriptions for one year from the first day of the month pricing is listed. Exceptions to the 14 day prescription restriction for specific new drugs can be awarded by the Central Medical Council for products that meet either of the following two criteria:

- New drugs (e.g. compound drugs) with APIs that have the same effect, efficacy, dosing and administration as approved products with over one year of clinical experience
- New drugs where, based on its characteristics or the disease state, only over 14 day formulations exist and the safety of over 14 day administration has been confirmed

6.2 Medical Drugs/Medical Devices | Generic Drugs

Definition of Generic Drugs

Medical drugs have a period when the pharmaceutical company which first developed it has the exclusive rights for manufacturing and marketing them (period during which patent is in effect and reevaluation period for verifying efficacy and safety), and the drugs manufactured and marketed during this period are called original drugs.

Once this period expires, based on the publicized patent information, other pharmaceutical companies can manufacturer/market drugs which contain the same active ingredients. These drugs thus launched which contain the same active ingredients as the original drug are called generic drugs.

The characteristics of generic drugs are that while they have the same active ingredients and as a general rule the same efficacy, effect, dosage and administration as the original drug, their prices are lower. Also, while the original drugs are exclusive to the pharmaceutical company which developed it first, in many cases, generic drugs are manufactured and marketed by several pharmaceuticals. In the Western market, as these drugs are often prescribed using the generic names of the active ingredients (as opposed to original drugs which are often called by their brand names), they have been called generic drugs, and this term has become popular in Japan as well.

Efficacy and Safety of Generic Drugs

To manufacture and market generic drugs, unlike the original drug, there is no need to conduct clinical trials to verify efficacy and safety of the active ingredients, as efficacy and safety have already been established in the approval process of the original drug. However, even if the drug has the same active ingredients, if it is made by a different

manufacturing process, it may not have the same mode of action. Therefore, in the manufacturing and marketing of generic drugs, they are examined to see if the efficacy and safety are equivalent to those of the original drug. Evaluation criteria consist of “Test Procedures and Acceptance Criteria”, “Stability Test”, “Bioequivalence Studies”. If, based on these criteria, the generic drug is proved to be the same as the original drug, its efficacy and safety are cleared of any issues and the generic drug is eligible to get approval.

Perspective: MHLW’s position on generic drugs

In Japan, thanks to the universal national health insurance system, every citizen has equal access to a necessary and high quality medical treatment by paying only a certain percentage of the medical cost from his/her own pocket. On the other hand, with the advancement of medical technology and fast-aging society, Japan’s healthcare cost keeps on rising increasingly jeopardizing the sustainability of the national healthcare system. To maintain this universal healthcare system, sustain the quality of medical care and to drive efficiency improvement in the healthcare service, Japanese government has adopted a policy to encourage the usage of generic drugs.

In the cabinet decision in June 2015, it has set a target to achieve the share of generic drugs of 70% by 2017 and 80% by September 2020, with an ambition to achieve these targets as soon as feasible.

Prescription and Dispensing of Generic Drugs

In Japan’s National Health Insurance System, when physicians prescribe medical drugs, it is a common rule to use the generic name of the active ingredient. However, a physician can choose to put his signature on his prescription to specifically request the pharmacist to dispense original drug and not to change to generic drugs. Pharmacies, unless there are specific instructions from the physician, are encouraged to dispense generic drugs upon briefing to the patient and getting his/her consent. Incentives are set to make sure pharmacies will proactively choose to dispense generic drugs.

France is another market which adopts a similar mechanism of prescription and dispensing of generic drugs. In France, if a pharmacy refuses to dispense generic drugs in substitution to the original drug, the patient has to pay

100% out-of-pocket at the pharmacy and apply for reimbursement later. This system is a strong incentive to drive penetration of generic drugs.

USA is an example of a market which adopts a different system than Japan. In the USA, the insurance policy held by the patient dictates which medical drugs he can use, giving limited freedom of choice to the physician or the pharmacist. The decision of which drug is to be adopted is made by the HMO, the insurer, in negotiation with the pharmaceutical company.

Drug Price of Generic Drugs

As generic drugs don't require clinical trials and relieves the pharmaceutical company of large chunks of R&D expenses compared to an original drug, pharmaceutical companies can remain profitable even if the drugs prices are set lower than the original drugs. For this reason, in Japan's National Health Insurance System, it is a common practice that the reimbursement price of generic drugs is set significantly lower than that of the original drug, generally at 50% or less.

Furthermore, in Japan's NHI system, reimbursement prices are determined by taking actual market prices into consideration. Therefore, if several generic drugs which contain the same active ingredient exist in the market and price competition occurs in the market, cheaper reimbursement price will be set reflecting those circumstances.

Rules for Determining NHI Listed Price of Generic Drugs

Twice in a year (June and December), generic drugs have opportunities to get screening for approval and inclusion in the NHI reimbursement list.

If generic drugs are to be included in the NHI list for the first time, the basic rule is to set its price at 50% of the original drug, with two exceptions: the price of internal medicine is set at 40% of the price of the original drug if the number of items proposed for inclusion in the NHI list exceeds 10 items; and price of biosimilar is to be set at 70% of the original drug.

Furthermore, after the initial inclusion in the NHI list, drug prices will be gradually reduced at each of the biannual drug price revision which target all listed products in the NHI list, according to the changes in the actual market price. In cases where several generic drugs exist, a policy is implemented for setting one price per each price range, as described below:

- Generic drugs whose price is estimated to be less than 30% of the highest price are included in the list at single price (weighted average)
- Generic drugs whose price is estimated to be 30% or higher but less than 50% of the highest price are included in the list at single price (weighted average)
- Generic drugs whose price is estimated to be 50% or higher of the highest price are included in the list at single price (weighted average)

6.3 Medical Drugs/Medical Devices | Non-prescription Drug

Segmentation of prescription drugs and non-prescription drugs

Apart from prescription drugs which are dispensed by the pharmacist and taken by the patient according to the prescription issued by a physician/dentist, drugs requiring guidance and non-prescription drugs exist which general public may purchase directly at pharmacies and drugstores and use at one's own discretion.

As non-prescription drugs can be purchased/taken by the general consumer at his/her own discretion, sellers are required to provide information to the buyer, and they are divided into Class 1, Class 2 and Class 3 based on risk level, each category with a defined degree of necessity of providing information.

- Class 1 Drugs : Drugs for which pharmacists are required to provide information and only under a pharmacist's management and guidance can be sold/handed over
- Class 2 Drugs : Drugs which can only be sold and handed over at stores where pharmacists/registered sellers are working full time, and providing information has to be done on best effort basis.
- Class 3 Drugs : Drugs whose risk level is the lowest. Unless the buyer directly requests for it, they can be sold without any legal obligation to provide explanation in particular.

Drugs requiring guidance are, distinct from non-prescription drugs, categorized as "quasi-prescription drugs", and Switch OTC Drugs, which have just been switched from prescription to non-prescription drug and thus haven't been certified risks as non-description drug, as well as Direct OTC Non-prescription Drugs, which have never been used as prescription drugs, fall into that category.

| OTC Drug Categorization | | Expert | Explanation from Salesperson to Customer | Response to Customer Request for Consultation | Distribution on the Internet/Mail-order |
|-------------------------|-----------|---------------------------------------|---|---|---|
| Behind-the-Counter Drug | | Pharmacist | Provide written information face-to-face (Obligation) | Obligatory | Not permitted |
| Non-prescription Drug | Category1 | | Provide written information (Obligation) | | Permitted |
| | Category2 | Pharmacist or registered sales person | Best efforts | | |
| | Category3 | | Not stipulated in law | | |

The term "OTC pharmaceutical" refers to pharmaceuticals without any significant action on the human body in terms of its efficacy and effect, intended for use with options selected by a consumer based on information provided from a pharmacist and other medical professionals.

6.4 Medical Drugs/Medical Devices | Medical Devices

Medical Device Classification and Approval

In Japan, medical devices are defined as approved medical products with clearly defined structure, method of use, effect and performance to be used with objective of either “diagnosing, treating or preventing disease” or “impacting the structure or function of the human body.”⁹⁴

Medical devices, in Japan, are classified into the following four categories based on their intended use and safety risk. Approval requirements for medical devices vary by category

In particular, category III and IV medical devices with the largest risks require PMDA approval.

| Category | | Type of Medical Device | Approval Requirement |
|--------------------------------------|-----------|---|--|
| General Medical Devices | Class I | Medical devices with extremely low risk in the event of defect / failure: <ul style="list-style-type: none"> Enteral infusion sets, nebulizer, x ray film, blood gas analyzer, surgical non-woven products, etc. | <ul style="list-style-type: none"> Self declaration |
| Controlled Medical Devices | Class II | Medical devices with relatively low risk in the event of defect / failure: <ul style="list-style-type: none"> X-ray imaging device, electrocardiograph, ultrasonic diagnostic device, injection needle, blood collection needle, vacuum blood collection tube, infusion set for infusion pump, Foley catheter, hearing aid, household massager, etc. | <ul style="list-style-type: none"> Third Party Certification |
| Specially Controlled Medical Devices | Class III | Medical devices with relatively high risk in the event of defect / failure: <ul style="list-style-type: none"> Particle beam therapy equipment, artificial dialyzer, epidural catheter, infusion pump, automatic peritoneal perfusion device, artificial bone, artificial heart-lung machine, artificial respirator, etc. | <ul style="list-style-type: none"> Minister's Approval Third Party Certification |
| | Class IV | Invasive medical devices with life threatening risk in the event of defect / failure: <ul style="list-style-type: none"> Pacemaker, coronary stent, artificial blood vessel, PTCA catheter, central venous catheter, etc. | <ul style="list-style-type: none"> Minister's Approval |

⁹⁴The Japan Federation of Medical Devices Association "On Medical Equipment" <http://www.ifmda.gr.jp/device/about/> (Accessed 2018, Apr. 30)

Medical Device Reimbursement Assessment Categories

Under Japan's insurance scheme, the manner in which medical devices are reimbursed and priced depends on its reimbursement assessment category⁹⁵

- Medical devices within the A1, A2, and A3 categories covered within the technical fee for specific procedures and cannot be reimbursed separately
- Medical devices within the B1, B2 and B3 categories are referred to as Specialty Treatment Materials that are directly reimbursed separately from technical fees based on reimbursement prices set by technical category
- Medical devices within the C1 and C2 categories are, similar to B category devices, directly reimbursed separate from any technical fees. However, as they do not fit existing technical categories upon approval, the creation of a new technical category is required. Furthermore, C2 medical devices also require the creation of a new technical category as well
- B3, C1 and C2 medical devices require approval by the Chuikyo

| Assessment Category | | Reimbursement Method |
|---------------------|---|---|
| A1 | Comprehensive | Items covered by the technical fee |
| A2 | Specifically Comprehensive | Items that are covered by existing, specific technical categories |
| A3 | Existing Technology w/revision | Items that are covered by existing, specific technical categories (Require changes to consideration items) |
| B1 | Existing Technical Category | Specialty Treatment Material that is directly reimbursed based on existing technical category separately from technical fees |
| B2 | Existing Technical Category w/ revision | Specialty Treatment Material that is directly reimbursed based on existing technical category separately from technical fees (Requires revision of existing technical category) |
| B3 | Fixed Period Enhancement Premium | Specialty Treatment Material that is evaluated by awarding temporary premiums based on existing technical category |
| C1 | New Function Product | Products that need a new function classification and have already been evaluated for technical fee |
| C2 | New Function / Technology Product | Products that need a new function classification and have not yet been evaluated for technical fee |
| F | Not suitable for NHI reimbursement | |

Reimbursement Prices for New Medical Devices

Unlike pharmaceutical products which are reimbursed by product, medical devices are reimbursed based on the technical category.

New medical devices are priced either via the "comparable technical category method" if there is an existing technical category exists for similar products, or via the "cost based method" when there is no existing technical category. Medical device reimbursement prices are revised concurrently with the periodic reimbursement

⁹⁵ Ministry of Health, Labour and Welfare "Outline of the 2018 Revision of the Medical Products and Equipment Insurance System" <https://www.idta.org/pdf/20180404-3.pdf> (Accessed 2018, May. 1)

revisions.⁹⁶ Similar to pharmaceutical products, medical device price revisions are decided primarily on the variance between the reimbursement price and actual market prices based on an acceptable margin including consumption tax of 4%.

In addition, the MHLW has also implemented medical device reimbursement pricing policies to promote innovation.

- Challenge Filing: Mechanism to subsequently file for a new technical category post approval based on real world data
- Fixed Period Enhancement Premium: Additional price premium awarded for 2 reimbursement periods to products able to replace an existing technical category
- Technical Category Exception: Mechanism applied to highly innovative or Sakigake products in which prices are maintained at a higher level for 2 reimbursement periods separately from other follow on products within same technical category

Going forward, similar to pharmaceutical products, to control reimbursement prices, it is expected that health economics outcome considerations may also be considered when deciding medical device pricing.⁹⁷

⁹⁶ Ministry of Health, Labour and Welfare "2016 Revision of the Medical Products and Equipment Insurance System" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000114377.pdf> (Accessed 2018, Apr. 30)

⁹⁷ Ministry of Health, Labour and Welfare "Outline of the 2018 Revision of the Medical Products and Equipment Insurance System" <https://www.idta.org/pdf/20180404-3.pdf> (Accessed 2018, May. 1)

7.1

Financing | Trends in Medical Expenditures

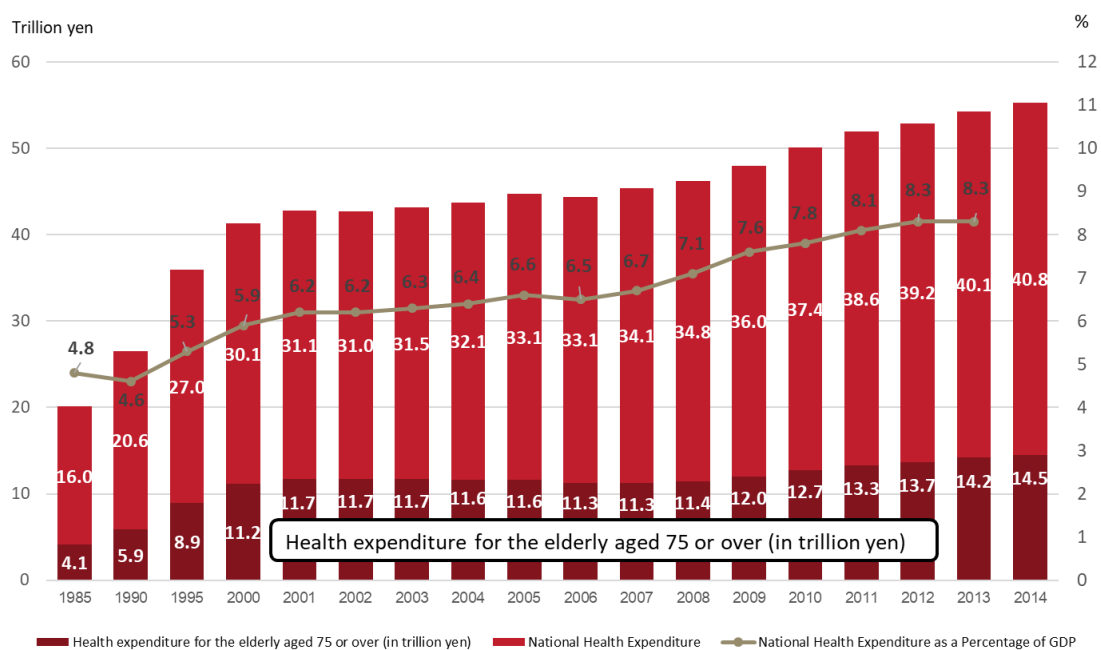
Medical expenditures in Japan for FY2016 totaled 41.3 trillion yen (according to preliminary reports), approximately 0.2 trillion yen less than the total from the previous fiscal year. This preliminary figure is also referred to as approximate medical expenditure because it excludes expenditures stemming from work-related injuries or those paid entirely out of pocket by individuals. The growth rate of the approximate medical expenditure compared to the previous fiscal year was -0.4%. Rather than being frequently observed, this negative annual growth rate was an isolated occurrence, likely due to significant increases in expenses, particularly in 2015, related to antiviral drugs for treating viruses such as Hepatitis C, followed by a year in FY2016 that saw such changes as the revision of medical service fees as well as significant decreases in expenses for antiviral drugs.⁹⁸ In this section, "medical expenditure" refers to the actual cost incurred at medical facilities for examinations, medications, and treatment for sickness or injury. Note that while "medical expenditure" refers to approximate medical expenditure, "national medical care expenditure" refers to the estimated costs of treating injuries and diseases covered by insurance. Specifically, "national medical care expenditure" includes costs for medical and dental treatment, pharmaceutical dispensing, hospital room and board, in-home nursing care, and treatments such as those from chiropractors/acupuncturists.

⁹⁸ Ministry of Health, Labour and Welfare "FY2016 Medical Expenditure Trends-MEDIAS-"
http://www.mhlw.go.jp/topics/medias/year/16/dl/iryouhi_data.pdf (Accessed 2018, Jan.25)

Factors Behind Rising National Medical Care Expenditures

As shown in Figure 7-1-1, national medical care expenditure increases every year. These national medical care expenditure figures represent estimates of the cost of treating injuries and illnesses at medical facilities within each fiscal year. Factors contributing to rising expenditures include those common among developed economies such as population aging, advances in medical technology, and increased demand for healthcare. In 2015, approximately 60% of national medical care expenditure was incurred by people aged 65 and over.⁹⁹ This group composed approximately 27.3% of the total population as of October 1, 2016. It is predicted that amidst a shrinking population, the rate of population aging will continue to rise, bringing the percent of people aged 65 or over to 33.3% or 1 in 3 by 2036 and resulting in even higher national medical expenditure.¹⁰⁰

Figure 7-1-1: Trend in National Medical Expenditure Growth



Source: Created by Specified nonprofit corporation Health and Global Policy Institute based on data from the "Trend of medical expenditures in 2016" report by the Ministry of Health, Labour and Welfare

⁹⁹ Ministry of Health, Labour and Welfare "Basic Document on Health Insurance" http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/kiso_h27.pdf (Accessed 2017, Jan.25)

¹⁰⁰ Cabinet Office "FY2017 White Paper on the Aging Society" http://www8.cao.go.jp/kourei/whitepaper/w-2017/zenbun/pdf/1s1s_01.pdf (Accessed 2017, Jan.25)

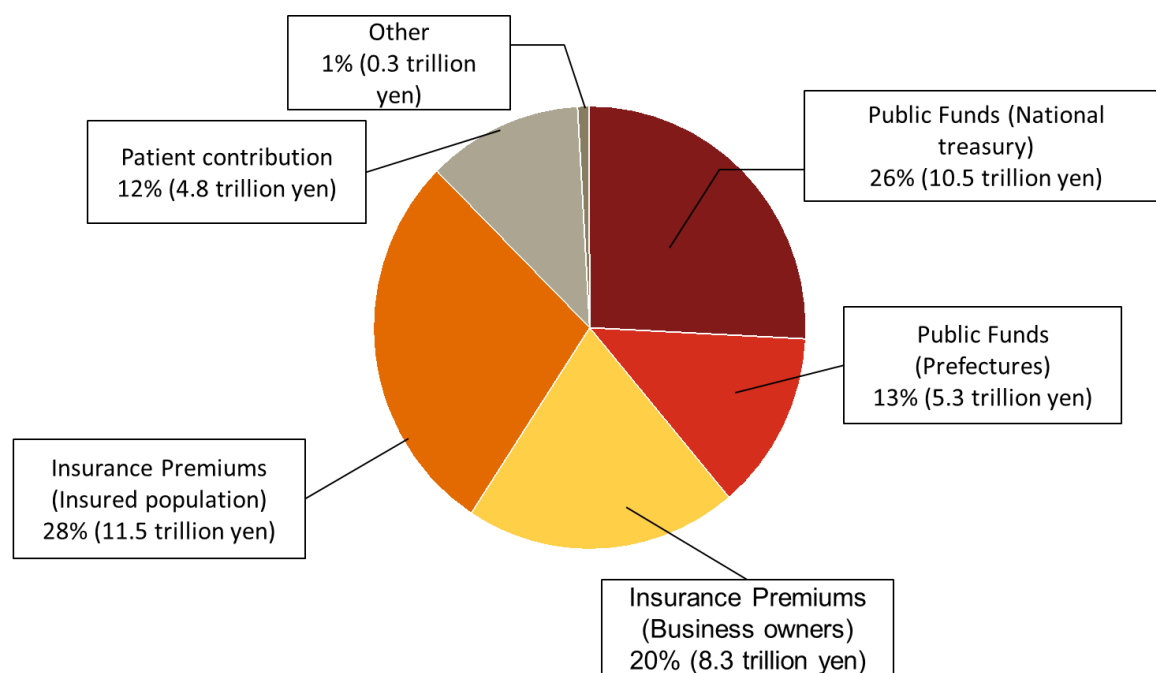
National Medical Care Expenditure by Funding Source

The topic of national medical care expenditure is crucial for considering the sustainability of Japan's universal health insurance system. This is especially clear when viewing national medical care expenditure by funding source—a total of 87% of all expenditures are funded via public sources (government funds and insurance premiums). The complete breakdown of funding sources is shown in Figure 7-1-2.

Compared to other developed nations, Japan spends relatively little on healthcare in absolute terms; however, total spending on healthcare as a proportion of GDP is higher than the OECD average. By this measure, Japan ranks sixth, just behind the United States, Switzerland, Germany, Sweden, and France.¹⁰¹ That said, it should be noted that the OECD calculates healthcare spending as the sum total of not only national medical care expenditures for treatments reimbursed by health insurance, but also spending on over-the-counter medications (OTCs), long-term nursing care, preventative measures (vaccinations, checkups, etc.), natural childbirth, and optional hospital bed upgrades.

In recent years, total healthcare spending as a proportion of GDP has been increasing. Starting in 2006 and heading into 2016, healthcare spending as a proportion of GDP increased from 7.8% to 10.9%, a number that far surpasses the 2016 OECD average of 9.0%.¹⁰² Japan is one of only a small number of OECD member economies that has reported rising healthcare spending as a proportion of GDP since 2009. However, the OECD does predict that healthcare spending in Japan will gradually level off in the future.

Figure 7-1-2: National Medical Expenditure by Funding Source in FY2014



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "State of National Medical Expenditure in 2014" report by the Ministry of Health, Labour and Welfare

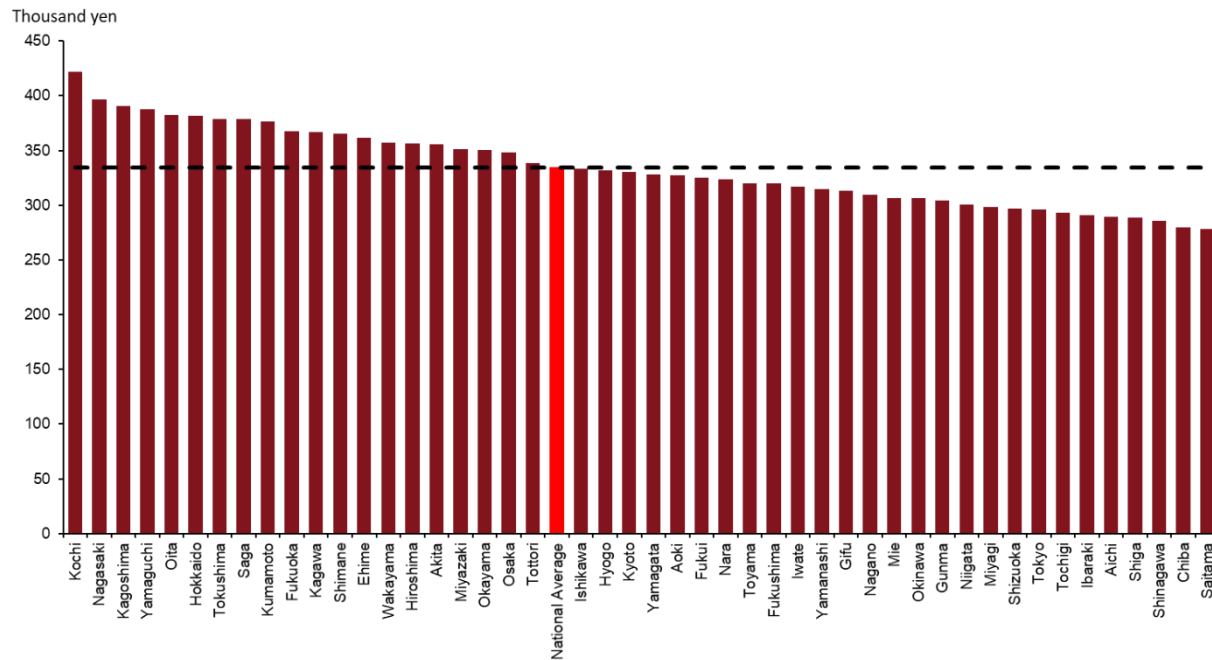
Japan faces regional disparities in national medical care expenditure. As shown in Figure 7-1-3, FY2014 medical care expenditure in Kochi Prefecture, the prefecture with the highest spending, was approximately 1.5 times higher than the expenditure of Saitama Prefecture, the prefecture which spent the least. The national government is currently aiming to reduce the age-adjusted per-capita national medical care expenditure gap by half in

¹⁰¹ OECD "Health at a Glance 2017: OECD Indicators" <http://www.oecd.org/japan/Health-at-a-Glance-2017-Key-Findings-JAPAN-in%20Japanese.pdf> (Accessed 2017, Jan.25)

¹⁰² OECD "Health Statistics 2017" http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT (Accessed 2017, Jan.25)

response to this issue. Regional Medical Care Visions, Medical Cost Optimization Plans, and the strengthening of incentive measures for health-promotion as discussed in Sections 4 and 5 are all parts of the effort being made to resolve this problem.

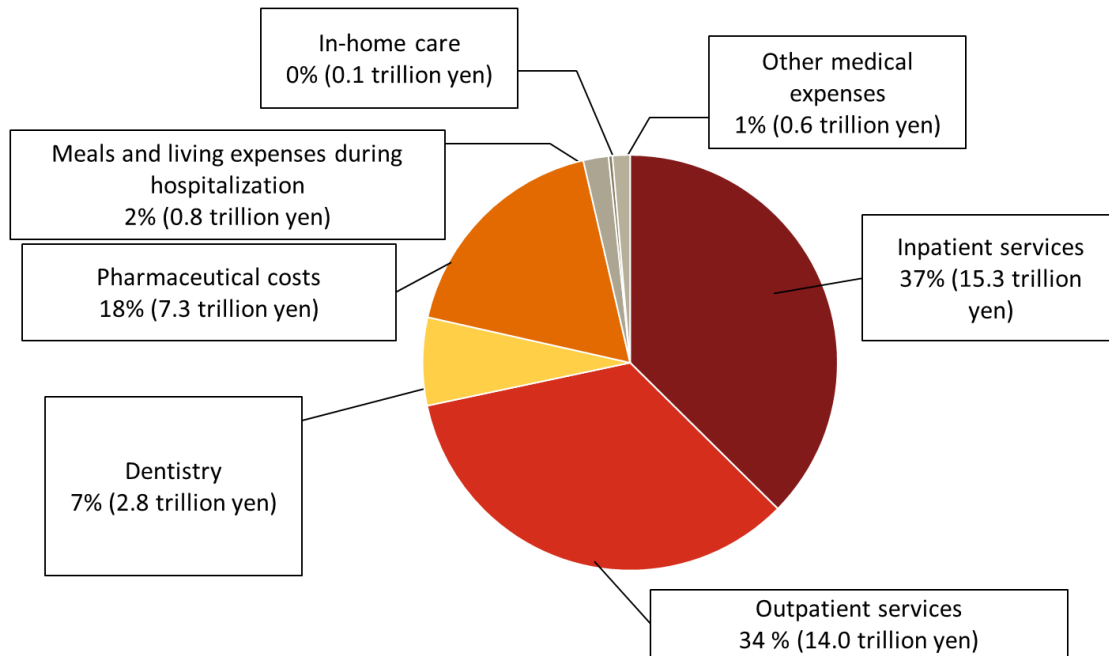
Figure 7-1-3: Per Capita Medical Expenditure by Prefecture, FY2014



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "State of National Medical Expenditure in 2014" report by the Ministry of Health, Labour and Welfare

In terms of the ranking of national medical care expenditures by type of care, as shown in Figure 7-1-4, in FY2014 inpatient expenditures ranked highest, accounting for 37% of the total, followed by outpatient expenditures at 34%, and pharmacy dispensing expenditures at 18%. As touched upon in Section 4, one factor that has been identified behind the high inpatient expenditures is the longer than average length of hospitalization in Japan compared to other countries.

Figure 7-1-4: National Medical Expenditure by Medical Service Type, FY2014



Source: Created by Specified nonprofit corporation Health and Global Policy Institute and PwC Consulting LLC, Strategy& based on data from the "State of National Medical Expenditure in 2014" report by the Ministry of Health, Labour and Welfare

7.2 Financing | The Medical Service Fee System

“Medical service fees” refers to the fees that healthcare providers charge for medical services and pharmaceuticals covered by health insurance plans. These fees are set through a medical service fee point system in which 1 point equals 10 yen. All healthcare providers throughout Japan are required to comply with the medical service fee points and calculation requirements for health services, medical devices, and pharmaceuticals that are set by the MHLW, and providers are prohibited from charging medical fees in excess of these set amounts. In general, providers may not provide patients with combinations of insurance-covered and non-covered treatments (mixed medical treatments); however, mixed medical treatments are allowed for situations covered by the Special or Specified Medical Care Coverage System. The Special or Specified Medical Care Coverage System applies to situations involving advanced treatments and Patient-Proposed Health Services (PPHS) that are under evaluation for insurance coverage as well as elective treatments not intended for coverage.¹⁰³

<Column> Has episode-based payment resulted in lower costs?

Another goal of the Japanese system of episode-based payment was to drive down costs, but is that goal being achieved? Actually, there is a possibility that health care costs have increased as a result of DPC. While DPC was successful in reducing the average length of hospital stay, an increase in the per-diem rate of inpatient care created an incentive for hospitals to increase the number of inpatients. The introduction of DPC also saw the start of “DPC consulting” services that, in some cases, help facilities manipulate coding, or up-code, in order to yield greater returns per patient.

Structure of the Medical Service Fee System (FFS and DPC)

The medical service fee system includes a Fee-For-Service (FFS) system and a Diagnosis Procedure Combination (DPC) payment system.

Since the foundations of the current health insurance system were established in 1961, medical service fees have come to be based on a Fee-For-Service (FFS) system. The medical service fee system reimburses providers from insurance funds based on medical service fee points, calculated by each medical facility according to the insurance-applicable medical services, pharmaceuticals, and medical devices actually provided.

Introduction of the DPC System

The Diagnosis Procedure Combination (DPC) payment system is a medical service fee framework unique to Japan that emerged in the early 2000's amidst growing concerns over healthcare costs, lengths of hospitalization, and the healthcare demands associated with the rapid aging of the population.

From 1998 to 2004, an episode-based payment system for acute inpatient care was introduced on a trial basis at 10 major hospitals. During this trial period, the current DPC framework using a per-diem payment system (PDPS) was introduced. Among other things, the trial revealed that, regardless of large variations in length of hospitalization among patients with the same disease, compared to fee evaluation based on a retrospective, per-hospitalization method, fee evaluation based on a prospective, per-diem method resulted in smaller gaps between the total service fee points and the actual resource costs and provided an incentive to lower per-diem costs.

¹⁰³ Ministry of Health, Labour and Welfare “Regarding the Uninsured Medical Expense System” <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/20170925.pdf> (Accessed 2018, Jan.25)

Overview of the DPC System

The main purpose of the DPC system is to promote the standardization and transparency of healthcare. This system aims to improve the overall quality of healthcare while also addressing disparities among hospitals through the construction of an objective medical treatment information database that can be used to clarify medical outcomes and improvements. At the same time, the objective data of the DPC system gives patients the benefit of being able to reference standard treatments and pricing information. In addition, the DPC system is expected to contribute to shortening the average length of hospitalizations. As of April 1, 2016, approximately 55% of Japan's general hospital beds (490,000 beds in 1,667 hospitals) were covered by the DPC system.¹⁰⁴ Similar to the diagnosis-related groups/prospective payment system (DRG/PPS) introduced in the United States, the DPC system uses codes based primarily on combinations of diagnoses and procedures. There were a total of 4,244 such DPC codes as of April 2016.¹⁰⁵ The Japanese system is unique in that it includes per-diem, bundled/episode-based codes that are partially integrated with a fee-for-service (FFS) system. Medical fees for inpatient treatments that correspond to DPC diagnostic groups are calculated using a flat-rate, prospective payment system, while fees for non-corresponding services are calculated using an FFS system.

Fee Calculation Methods in the DPC System

Basic hospitalizations, screenings (including diagnostic imaging), injections, medications, and procedures valued at less than 1,000 points are subject to bundled/episode-based evaluations. Fees for these treatments and services are calculated based on a combination of DPC code-specific per-diem points, lengths of hospitalization, and medical facility coefficients.

Surgeries, radiation therapy, anesthesia, and treatments valued at 1,000 points or more are not subject to bundled/episode-based evaluations. Fees for these treatments and services are calculated using a Fee-For-Service (FFS) system.

In order to eliminate variations in the set coefficients assigned to medical facilities offering similar levels of care, the government reconsidered facility type-specific coefficients. Facility coefficients now include the Basic Coefficient, Function Evaluation Coefficient I, Function Evaluation Coefficient II, and the Provisional Adjustment Coefficient. In the past, there were just three types of facility-specific coefficients—the Adjustment Coefficient and the Function Evaluation Coefficients (I and II), but after the FY2012 revision to the medical fee calculation system introduced the Basic Coefficient, the Adjustment Coefficient began to be gradually replaced by the Basic Coefficient and Function Evaluation Coefficient II. In the FY2018 revision, the Adjustment Coefficient will be eliminated.¹⁰⁶

¹⁰⁴ Ministry of Health, Labour and Welfare "Outline of FY2016 Revision of Medical Service Fees (DPC System-Related Section)" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000115023.pdf> (Accessed 2017, Oct.27)

¹⁰⁵ Ministry of Health, Labour and Welfare "Outline of FY2016 Revision of Medical Service Fees (DPC System-Related Section)" <http://www.mhlw.go.jp/file/06-Seisakujouhou-12400000-Hokenkyoku/0000115023.pdf> (Accessed 2017, Oct.27)

¹⁰⁶ Ministry of Health, Labour and Welfare "Future Consideration of DPC System-Related Coefficients by Type of Medical Facility (Draft)" <http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000151103.pdf> (2018, Feb.2)

Basic Coefficient: Used for basic facility services that cannot be evaluated using Function Evaluation Coefficients.
Function Evaluation Coefficient I: Used when considering the entirety of the medical facility as a service provider, including its personnel organization, facilities, and structure (structural factors).
Function Evaluation Coefficient II: Used when considering incentives (for roles/ functions that medical facilities should take on) to improve medical delivery system efficiency through the use of DPC/PDPS.

Fee calculation methods also vary according to the stage of hospitalization of which there are three. The flat, per-diem fee during Stage I, the earliest stage of hospitalization, is set higher than for Stages II and III. Stage II includes days spent in the hospital past Stage I through the day representing the national average length of stay according to DPC data. Although flat fees within this stage vary according to each diagnostic category, after taking into account the average per-diem medical resources used, fees in this stage are effectively lower than fees in Stage I. In Stage III, the final stage specified within the DPC system, per-diem rates are set even lower than in Stage II.¹⁰⁷ In exceptional cases, when hospitalizations extend beyond the end of Stage III, all additional medical service fees are then calculated using the fee-for-service (FFS) system.

There is much debate within Japan on whether the DPC system is producing results in line with its original purpose. The DPC was created through a unique combination of the United States' PPS and FFS systems. There have been many analyses published concluding that the use of this system cannot be linked to cost reductions as well as many publications arguing that the PPS system needs to be applied to an even greater range of services.

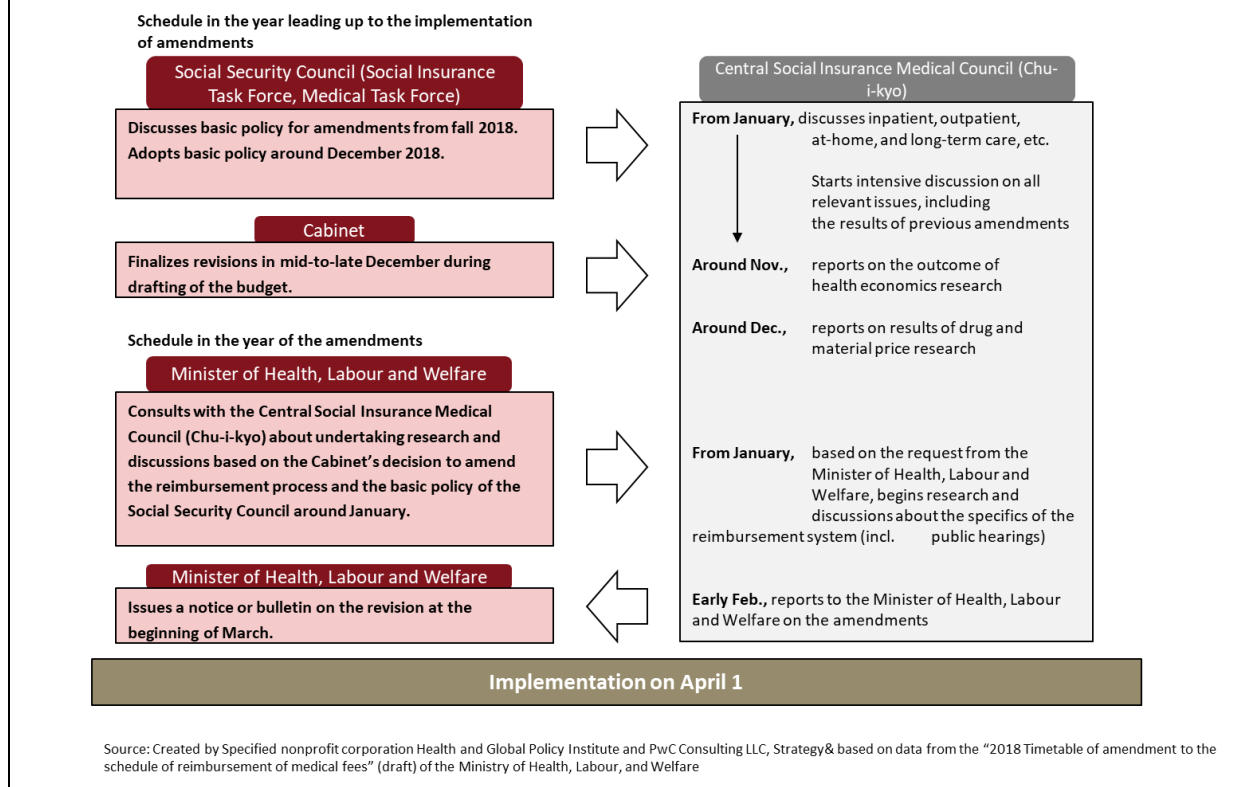
¹⁰⁷ Ministry of Health, Labour and Welfare "Overview and Basic Approach of the DPC System (DPC/PDPS※)) <http://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/0000186975.pdf> (Accessed 2018, Feb.2)

The Revision Process for Medical Service Fees

(Road to revision approval via the Central Social Insurance Medical Council and Social Security Council)

Japan's medical service fee system is currently revised once every two years. When under revision, discussions are held in a variety of domains. As shown in Figure 7-2-1, over the course of the revision process, the Social Security Council, the Cabinet, the Minister of Health, Labour and Welfare, and the Central Social Insurance Medical Council (Chu-i-kyo) hold discussions and set goals. For instance, the Chu-i-kyo not only makes proposals over the course of this process, it also holds discussions and responds to inquiries from the Minister of Health, Labour and Welfare regarding medical service fees, regulations for medical facilities, and health professionals authorized to accept insurance. The Chu-i-kyo is composed of both members representing insurers, the insured, and employers (on the payer side), as well as members representing doctors, dentists, and pharmacists (on the medical side), and others representing the public interest.

Figure 7-2-1: Schedule for amendments to the medical fee reimbursement process



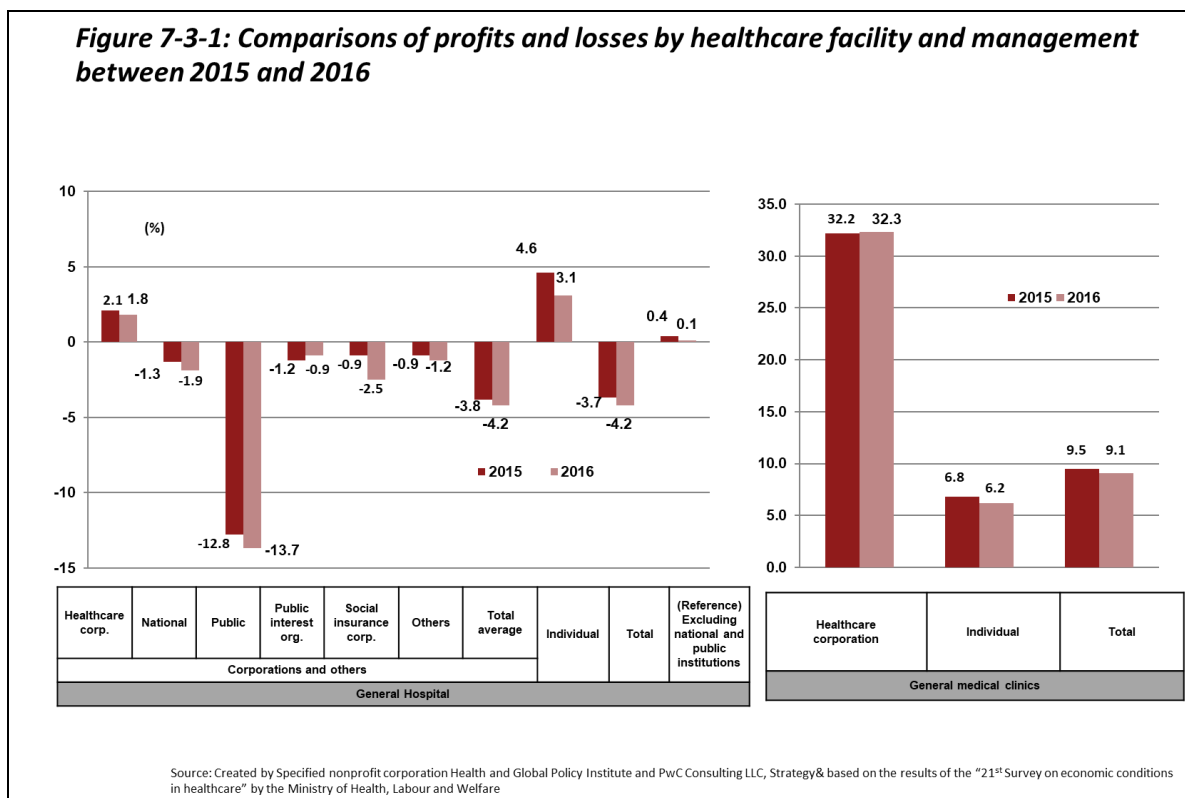
7.3 Financing | Medical Facility Management

Medical facility revenue is composed of the total remainder after subtracting patient copayments and claims paid by insurance examination and payment facilities. This revenue does not go only to physician salaries. It is also used to cover hospital and clinic overhead, as well as the cost of purchasing pharmaceuticals, the cost of purchasing medical supplies, and the cost of facility maintenance.

Data on Japanese Medical Facilities

MHLW conducts a regular Survey on the Current State of Health Economics that examines the state of healthcare management at hospitals, medical clinics, dental clinics, and insurance-covered pharmacies. This survey is conducted every two years, and the results inform future medical service fee revisions.¹⁰⁸

Figure 7-3-1 shows profits and losses in FY2015 and FY2016 by medical facility type. The profit margin in FY2016 for hospitals overall was -4.2%, although this figure jumps to +0.1% when excluding national public hospitals. This is thanks to the positive effect of the FY2014 medical service fee revision on most hospital profit margins (+0.4% → +0.6%). Many hospital types are losing money overall, with public hospital profit margins being particularly low.



¹⁰⁸ Ministry of Health, Labour and Welfare "Survey on the Current State of Health Economics (Survey of medical facilities etc.)" <http://www.mhlw.go.jp/bunya/iryouhoken/database/zenpan/iryoukikan01.html> (Accessed 2017, Dec.14)

Although most public hospitals are in debt, as these hospitals bear responsibility for pro bono care as well as most care in remote areas, a portion of their debts are subsidized by tax revenues. Reasons for the high amounts of debt among public hospitals include cost-related problems as well as shrinking patient numbers. Especially at smaller public hospitals, although average service prices are increasing, profits are decreasing due to falling patient numbers.¹⁰⁹

In addition, salary rates, pharmaceutical costs, and depreciation expenses are higher at public hospitals compared to hospitals in general. In response to this situation, actions are being taken based on the "New Public Hospital Improvement Guidelines" including initiatives for the improvement of healthcare management, adjustments to hospital bed functions in consideration of regional healthcare needs, and downsizing.

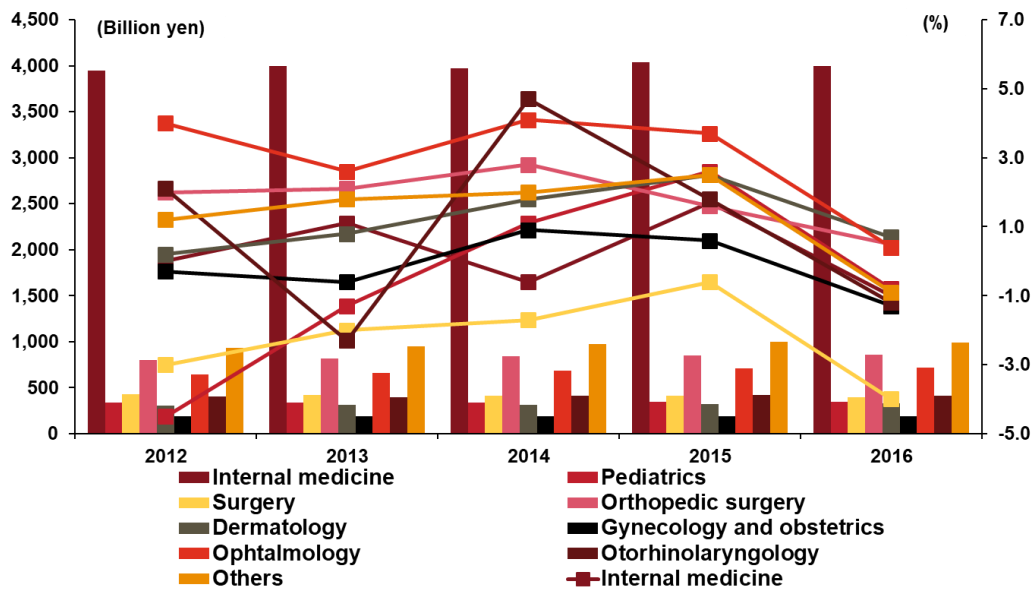
Meanwhile, as in previous years, medical clinics remain profitable. That said, profit margins are shrinking. At the time of the last revision in FY2014, the clinic profit margin was 15.5%, but in FY2016, it was 9.1%.

It's important to keep in mind that the facilities sampled for the Survey on the Current State of Health Economics vary between surveys, so it is not possible to directly compare recent survey results with past results. Furthermore, since the Survey is set to only a sampling of medical facilities, there is always the chance that results do not accurately reflect the true distribution of profit margins across Japan.

¹⁰⁹ Ministry of Finance "Supplementary Explanation Document (FY2018 Revision of Medical Service Fees, 21st Survey on the Current State of Health Economics)" http://www.mof.go.jp/about_mof/councils/fiscal_system_council/sub-of_fiscal_system/proceedings/material/zaiseia291108/01.pdf (Accessed 2017, Dec.14)

Figure 7-3-2 shows medical expenditures by specialty. Expenditures vary among specialties, with otolaryngology and otolaryngologic surgery expenditure trends differing most greatly from trends related to other specialties. Pediatrics, pediatric surgery, and obstetrics/gynecology have consistently shown negative growth rates. Internal medicine ranks highest in terms of total expenditures due to recent measures such as the promotion of primary care, and because this specialty treats the largest number of patients. In comparison, expenditures were more than four times lower for orthopedic surgery, the specialty with the second-highest expenditures.

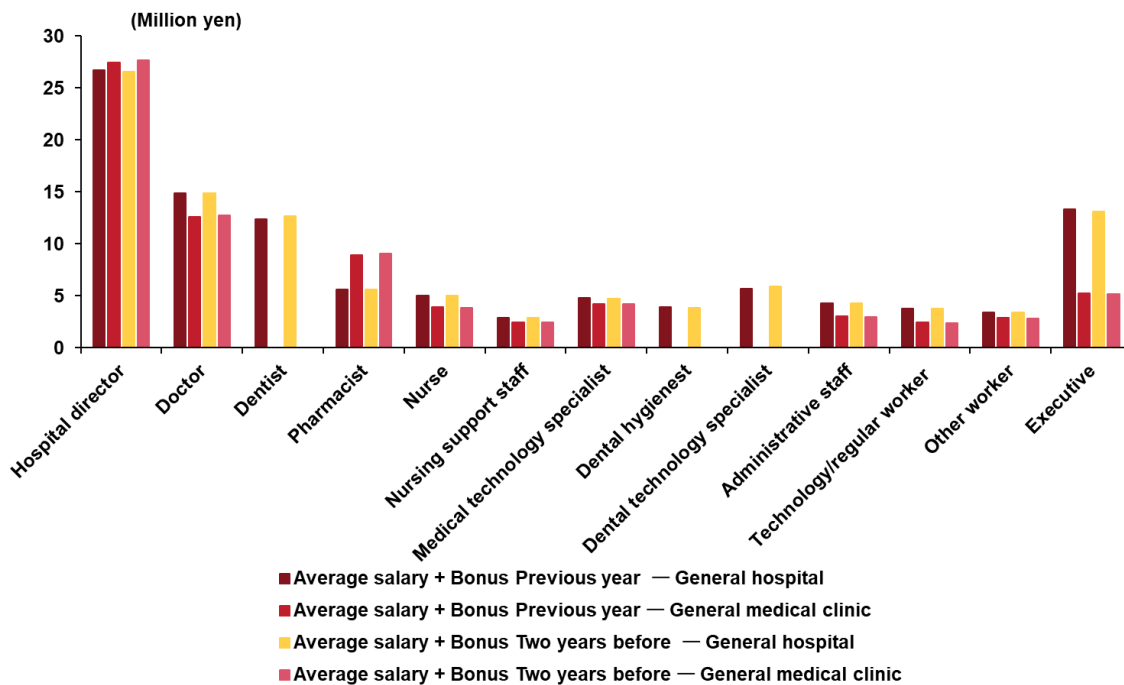
Figure 7-3-2: Clinical, inpatient, and outpatient medical fees, and fee growth rates per major medical specialization



Source: Created by Specified nonprofit corporation Health and Global Policy Institute based on the "2016—Trends in medical expenditure" report by the Ministry of Health, Labour and Welfare

Looking at average remuneration (salaries and bonuses) for full-time employees working at medical facilities, as shown in Figure 7-3-3, totals are particularly high for hospital directors and physicians at both hospitals and medical clinics, especially compared to other full-time employees. Other than full-time pharmacists and executives, there are not large differences within professions depending on the facility type. This was true of hospitals and medical clinics in general even when comparing data from one fiscal year to the next.

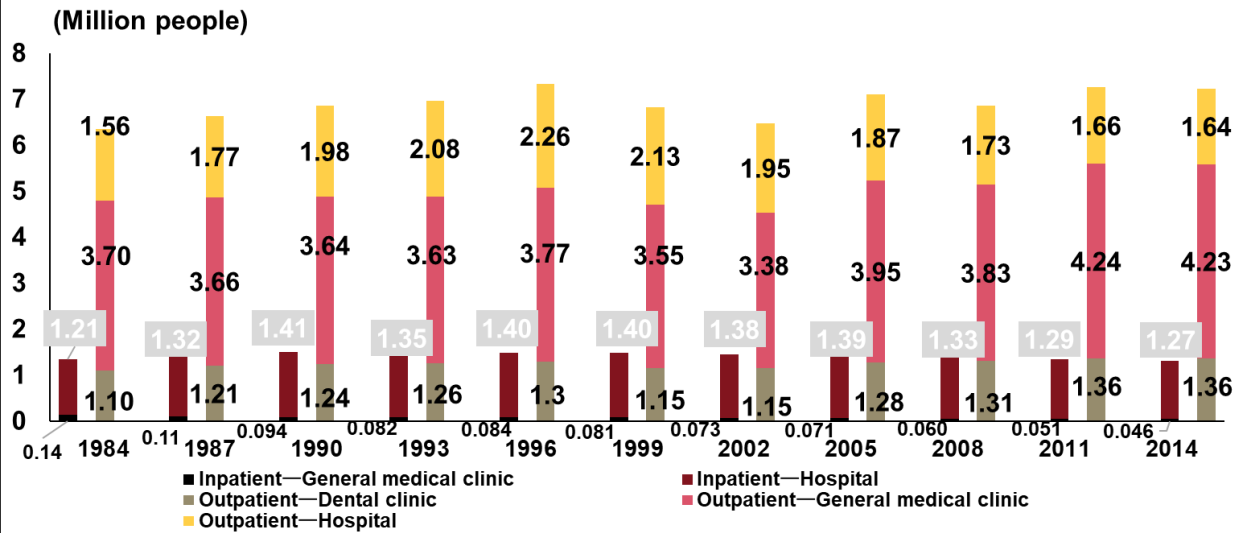
Figure 7-3-3: Per-capita salary and bonus for full-time workers in medical-related fields (FY2015-FY2016)



Source: Created by Specified nonprofit corporation Health and Global Policy Institute based on the results of the "21st Survey on economic conditions in healthcare" by the Ministry of Health, Labour and Welfare

Looking at the annual trends in terms of estimated numbers of patients per facility type (as shown in Figure 7-3-4), outpatients exceed inpatients. This is to be expected since the incidence of serious diseases requiring hospitalization is low compared to that of diseases for which outpatient care is sufficient. Both inpatient and outpatient numbers increased slightly from 1984 to 1996, but thereafter the number of outpatients leveled off. Since 2011, the number of hospitalized patients has reached a level nearly equivalent to the level in 1984.

Figure 7-3-4: Annual Trends in number of patients per facility type



Source: Created by Specified nonprofit corporation Health and Global Policy Institute based on the results of the "2016 survey on patients" by the Ministry of Health, Labour and Welfare

8. Indications for the Future

As we move into the future, we can anticipate changes to continue in the healthcare arena.

As described in the MHLW's Health Care 2035 report, the following core trends impacting Japan now and into the future are expected to drive the way for change into the future. These are: 1) demographic shifts, 2) accelerating urbanization, 3) disease structure, and 4) the increasing impact of technological change. Each of these will have different impacts on the healthcare system in Japan.

Demographic Shifts

Let's start with demographic shifts. Globally, we are seeing the ageing of mature economies and population growth in development economies. In Japan, this demographic shift is visible in two specific ways – the ageing and decrease of the population, and the impact to healthcare will be dramatic. We will see changing medical needs with expenditure continuing to increase, and the proportionality of diseases will shift as the population ages.

Accelerating Urbanization

At the same time, we will see the acceleration of urbanization. In Japan, this is apparent as only Tokyo and Kanagawa prefectures are growing at the time this piece is being written. Furthermore, while populations are amassing in on Tokyo, Kanagawa and Saitama they are declining in the more remote areas of Japan as of October 30, 2018. These demographic changes are driving a shift in delivery of care. In remote areas, where there are fewer facilities, the need for technical support and “remote care” technologies are growing.

Disease Structure

In addition, as improved medical care drive changes in the disease structure, increasing the prevalence of diseases such as dementia and cancer, new approaches to community health are also emerging. This can take the form of interconnected patient data through new technologies such as cloud solutions which will allow for less in-hospital time and fewer healthcare workers. These changes will allow the elderly to stay at home longer before they are moved to nursing homes. But important challenges such as personal data privacy need to be overcome to develop the care delivery models of the future.

Technological Change

Finally, we will continue to see dramatic impacts from technological change. We have seen the rise of social media and the emergence of cloud technologies. Topics like “big data” and “analytics” have become ubiquitous. These technological changes are expected to create new opportunities to drive efficiencies in how healthcare is provided. A series of “new entrants” as diverse as technology companies, car manufacturers, communications companies and others are beginning to enter the market to take advantage of these opportunities and help drive change in healthcare. As a result, we are seeing a digital transformation of our healthcare system. With some of these technologies, how we handle our healthcare will be very different in the future. For example, imagine the impact of connecting apps on our phones with pharmacy information with our historical health information – including genetics and familial tendencies. If these can be done in a way that addresses privacy and security, a patient could visit any hospital in Japan and not need to repeat tests or face differing opinions.

Based on these trends, we can imagine dramatic changes coming in healthcare in Japan. They will be impacted by outside forces and regulated in the market through the government.

Conclusion

We hope you have found this document a resource for your education and reference on the Japanese healthcare system. HGPI endeavors to update this every few years as regulations evolve and trends impact the healthcare system and cause change.

Supplement: Interview – Envisioning future healthcare policies

Interviews were conducted with leading experts on the Japanese national healthcare system about the various challenges currently facing the system, the outlook for the future, and the best ways to reform the system. These interviews were used to enrich the information available on the JHPN website on healthcare policies as part of updates made to that site.

The main challenges identified in the interview were the change in the epidemiological profile of Japan alongside the rapid ageing of society, and the limited resources available to deal with those changes. The key to resolving these challenges is greater cooperation among academia, government, and the private sector.

The world is looking carefully at the policies of Japan, which is witnessing a more extreme rate of ageing and decrease in its birthrate than any other country, to see how it will develop its response to the incredibly urgent and complex challenges it faces.

Interview 1 (Kiyoshi Kurokawa – Health and Global Policy Institute; Chairman – National Graduate Institute for Policy Studies; Professor)

Challenges related to Japanese healthcare policies

- At the time the national universal healthcare system was established, it lent itself to evaluation. However, the system did not adapt well to changes in the times.
- There are many challenges faced by the healthcare system of Japan, including universal access, the evaluation of medical service quality, and ways to determine out-of-pocket medical expenses.

The biggest problem is universal access. For example, the number of CT machines available in Japan per million people is over three times higher than the number in other countries. This is but one example of how universal access can lead to waste. Despite the adverse effects, no one has come up with an adequate way of dealing with this issue.

Necessary measures to resolve challenges

- As Japanese society ages and chronic conditions become most prominent in the population's epidemiological profile, it will become necessary to have more general practitioners that patients can routinely consult with about the state of their health so as to prevent diseases or the worsening of symptoms.
- Although it is often claimed that there is a shortage of doctors in Japan, as a matter of fact, the number is sufficient. The apparent shortage, if there is a shortage, is related to the excessive number of hospitals that are being built. Given the certainty of the future demographic decline in Japan, as a response to this issue, a general practitioner system should be established. That system should assign doctors to each community as appropriate, and regional hospitals should move toward open systems that allow for them to share CT imaging equipment and other medical devices.
- In order to make effective use of otherwise limited medical resources, a plan must be devised to establish open relationships between healthcare institutions. This would allow each type of institution to achieve functional differentiation. In such a system, advanced medical care would be offered only in university hospitals. These hospitals would then discontinue the provision of outpatient services.

Aims for the Japanese healthcare system in the future

- The role of coordinator for efforts to draw up a mid-to-long term vision for the national healthcare system in Japan could be assumed by public institutions, but discussions about the actual implementation of that vision must involve multiple stakeholders, including patients. The importance of adopting a mid-to-long term perspective when planning for the future of healthcare cannot be stressed enough.
- A vision for the future already exists – “Japan Vision: Healthcare 2035.” The important task now is determining the steps and goals necessary for its realization. As a part of that, it is important to devise a process whereby individuals involved in the implementation of the vision become core actors with vital responsibilities over the twenty years of the vision's implementation.
- Government institutions must continuously communicate with the public and residents when implementing the vision.

- Henceforth, local governments – municipalities in particular – are set to play a much bigger role. Data on national health insurance, which is currently in the possession of municipalities, must be converted into a visible and accessible format and put to constructive use.
- When thinking about Japan's healthcare system, it is important to remember that under the integrated community care system, it is municipal governments that provide certain residence, nursing, preventative medicine, and lifestyle support services.

Contributions Japan could make to healthcare policymaking in other countries

- Even though the Japanese government possesses the ability to put new policies into practice, it lacks the mechanisms to discontinue existing systems. This means it does not learn from past mistakes. I would like other countries to learn from this aspect of Japan's system.

Interview 2 (Anonymous, Global Technology Company Executive)

Japan's Health Policy Challenges

- The key health policy challenge facing Japan is that the overall structure of the healthcare system is too expensive. These costs are exacerbated by the aging population, which is growing at a rate for which government and society are not prepared.
- To address this, it is important for Japan to shift away from the model it has today where people flock to large hospitals for care. The government is currently trying to encourage people not to do so by moving towards a community healthcare based model.
- However, Japan is running out of time. Innovative solutions are needed immediately. One of the biggest issues facing innovation in Japan is the lack of speed. While the problems of the burgeoning elderly population and cost structure have been understood for a long while, most entities and organizations, including the government, are not prepared to move fast enough - or flexibly enough - to deal with this challenge.

How the Private Sector can contribute to addressing Health Policy Challenges

- The manner in which people receive their healthcare or physical items that support their health all must change to address the challenges the healthcare system faces. This is a big focus area for the private sector, which is looking at how to use their specific capabilities to healthcare.
- While no one organization or individual has all of the solutions, companies, including non-traditional players in healthcare, have many assets and services they can utilize to help make these systemic changes happen.
- Furthermore, non-traditional players, such as IT companies, also bring different perspectives to innovation that can enable new solutions.
- Within the high-tech industry, the concept of velocity is important and is a term we use broadly. Philosophically, we approach innovation not by trying to solve for the end state right away, but by taking an iterative, agile, and experimental approach. While in medicine and healthcare, we need to be prudent, in spirit, we believe the key is to generate solutions quickly and iterate as we go.

How can stakeholders collaborate to transform health policy

- While many already see that change is required to address the problem of the increasing elderly population and cost structure, it is important to find likeminded stakeholders. It is important that we all share the same vision for the future and that there is a shared sense of urgency as well.
- Furthermore, particularly as a non-traditional player in healthcare, we must learn to work with traditional stakeholders. Not only are they unfamiliar with how we operate, but we are also unfamiliar with their concerns and way of working.
- As stakeholders, the solutions we build must be developed for the customers, the patients and physicians. We cannot develop a solution just because it is convenient for us. It is only by taking on this mentality that patients and physicians will believe that we are working with their interests in mind and that we can drive change.

How can Japan contribute to global health policy

- The manner in which Japan addresses the issue of its aging population is of interest to other countries. Furthermore, I believe Japan has the potential to be a leader in this space as it addresses this issue.

Interview 3 (Seigo Hara – MICIN Incorporated Company CEO)

Challenges related to Japanese healthcare policies

- The Japanese healthcare system faces three challenges. One, as income revenue and economic growth stagnate, the amount of resources available for social welfare is becoming limited. The second challenge is the ageing of the population and low birthrate, and the impact that this is having on the workforce, which in turn affects healthcare system finances. Third is the change in the overall epidemiological profile of Japan.

Necessary measures to resolve challenges

- It is important to make efficient and thrifty use of the limited resources available for spending on high quality medical care. To do so, we must first define “quality care,” and then we need to organize medical data based on that.
- As social welfare expenditures rise, it is necessary to collect data that can guide efforts to streamline resource allocation.

Challenges related to data use

— Data collection

- A challenge in medical data analyses is the actual lack of sufficient data. For instance, although some part of any medical consultation between a doctor and a patient is recorded as data, that data is not being stored in a form that is possible to analyze. Given these circumstances, data analyses will not return useful results for either patients or the public. This is a challenge now facing data analyses, the implementation of interventions based on such analyses, and the active use of data.

— Data use

- At the present time, what Japan needs is to establish acceptable methods and concrete policies for the use of data, and to clear up issues around personal privacy and intellectual property rights in order to further facilitate data use.
- While it is currently possible to analyze data, it is still not possible to feed the results of such analyses back into the medical field and use it to serve patients on an individual basis. Work is underway to generate health data for practitioners. The scope of that work should be broadened to cover all beneficiaries.
- When planning data use, it is very important to consider the merit its use might have from the perspective of the user, or the potential of the data to become the basis for the development of trustworthy services and products for eventual users. One way to make such a judicious use of data is for private companies to incorporate user perspectives into their designs and plans. From the perspective of policymaking, mechanisms should be put in place to provide a boost for private sector-based initiatives, and to create a basis for cooperation within the private sector.
- Entrepreneurs face the difficult task of drawing up outlines for the development of future businesses. Comparisons with other countries show that Japan has a higher number of CT and MRI machines given its total population. The massive amount of imaging data generated by such devices, and the amount of consistently formatted data Japan has on medical expenditures, may constitute a competitive advantage for Japan in the world.

Telemedicine

- The establishment of a system for telemedicine has advanced well over the past one or two years. Telemedicine might help to further promote the digitization of medical information that is not yet being recorded digitally. Thanks to telemedicine, data related to communications between doctors and patients will be created in places closer to patients.

- Alongside progress in telemedicine, not-yet-digitized data might eventually be put to constructive use. Nevertheless, much more effort still needs to be invested into spreading the custom of amassing data at the patient level. In addition, electronic medical records created by doctors are usually filtered, causing most data on communications between patients and doctors to be lost. It is thus important to always be aware of the fact that the extent to which available medical data approximates the reality of the information communicated by patients cannot be fully ascertained.

The form the national healthcare insurance system should assume in the future

- I believe the national healthcare insurance system in Japan is a good system. Japan tops the world in terms of indicators related to average life expectancy and infant mortality. This situation is believed to have been made possible by the establishment of universal access and safety nets in the healthcare system. Out-of-pocket medical expenditures are set at a fixed rate. These and other social benefits, which emanate from a system in which individuals may receive medical services regardless of their economic status, must be protected in the future. We also must protect the high-cost medical fees system.
- I think that it would be better if, in the future, the world adequately invested resources into higher value medical treatments. Payers will probably come to play a bigger role in Japan's medical system in the future. The system used in the Netherlands is a good example of a managed competition model. In the Netherlands, patients select payers, who in turn select providers, enabling the government to control risk.

Expectations of insurers

- It may be possible for policy-makers and service providers to work together to find innovative ways of allocating resources based on analyses of medical data and the claims data owned by insurance providers.
- In Japan, individuals, depending on age and occupation, may throughout their lifetime enroll in different insurance schemes. Data must be made consistent. It is necessary to investigate how to coordinate benefits between employee insurance schemes and regional healthcare insurance schemes so as to improve life expectancy and quality

Contributions Japan could make to healthcare policymaking in other countries

- Other countries will follow Japan in the future along the same path of declining birthrates, population ageing, and increasing strains on social security resources. Japan could serve as a model for such countries as they also seek to increase their own life expectancies and life satisfaction indicators.
- The National Clinical Database (NCD) includes a number of unprecedented cases in the world and surgery outcomes. As such, it is of great value. Since its claims data is to some extent gathered and stored within a database, it could be a source of competitive strength for Japan in the future.

Interview 4 (Akio Onishi, Visiting Professor – The University of Tokyo, Graduate School of Public Policy)

Challenges related to Japanese healthcare policies

- Ageing, the cost of healthcare, and human resource shortages are the chief challenges for Japan, but that has been known for some time. Nevertheless, it is important to pave the way for solutions to the problems underlying these challenges.
- For example, if we look at the problem of the declining birthrate and population ageing, there appears to be a trend toward investing a large amount of resources into ageing-related measures. With regards to the declining birthrate, a great deal is being done to resolve the issue of waiting lists at daycares and other challenges. It is important that a balance be struck between the amount of resources dedicated to resolving ageing-related issues and the amount of resources dedicated to the challenges of the declining birthrate.

Necessary measures to resolve challenges

- Concerning the provision of medical services, because medical service providers, including paramedics, exert a large amount of control over the quality of the healthcare system, it is important to provide them with incentives to deliver high quality care while monitoring the quality of the services they offer.

- Alongside the monitoring and evaluation of the quality of services offered, further in-depth discussions should be held on a system of incentives to improve the quality of these services further. Many countries are attempting to create such a system. Japan should follow suit by organizing spaces where this issue could be discussed.

How to assess the quality of medical care

- There are quite a few examples around the world of medical reforms being undertaken from the perspective of quality of care. This perspective places emphasis on monitoring burdens placed on medical care providers and patients by hospitalizations and medical services, using indicators such as readmission rates and statistics on convalescence management for evaluations. With regard to medical equipment, the skills of health professionals are also important to the effectiveness of such devices. The evaluation of such skills should adopt or incorporate a certain number of the indicators related to quality of care. When evaluating such skills, it is important to assess the extent to which they satisfy some indicators of Quality of Care. I look forward to further discussions about this issue.
- In recent years the concept of Health Technology Assessments (HTA) has been garnering greater attention in Japan; however, HTA evaluations and quality of care evaluations are not necessarily the same thing. Although HTA can be useful for measuring the cost-effectiveness of drugs, and a useful guide for the effective distribution of medical resources, it is important to consider the special characteristics of medical technology, medical devices, and medical resources respectively when implementing an HTA.

The form the national healthcare insurance system should assume in the future

- Japan's national health insurance system is excellent, and was designed to have a smooth management structure. What's more, the medical skills and motivation of doctors and allied health professionals can be praised highly. With regard to the system of universal healthcare, it is not only important to discuss whether it should be maintained or abolished, but also how to improve it.
- A major issue for Japan is how to expand the good service framework of one institution to other institutions, including regional institutions. At-home care and telemedicine are being implemented from the perspective of regional cooperation. It is important that Japan consider further solutions to make these services better and more efficient. In particular, there should be further discussions held on medical care and hospital management issues.
- Economic incentive frameworks to encourage greater regional collaboration should be considered further. It is also important to consider the provision of services and evaluation methods for the regions that will take part in such frameworks.

The form the national nursing-care insurance system should assume in the future

- In every region, people in need of nursing care are obtaining authorization under the national nursing-care insurance system and beginning to receive care services. Decentralization is leading to differences in authorization standards and in the characteristics of the services provided to patients.
- When users move outside of their area of residence, they often must wait for some time before they are able to be re-authorized and start availing themselves of available facilities and services. What's more, out-of-pocket costs may differ for the same service provided in different areas. It is therefore hard to say that it is easy to use nursing services across different municipalities.
- It is anticipated that in the future, the circumstances surrounding individuals and communities will change. Such changes could be due to people temporarily moving or changing residences, or because they acquire accommodations in different areas. Even in cases such as these, a mechanism should be developed to grant users a somewhat wide degree of freedom so that they can use nursing-care services smoothly.

The challenge of cooperation between Japan's medical and nursing sectors

- Despite the fact that in Japan, one is able to choose freely which medical institution one wants to receive medical treatment at, there are issues related to nursing care services that differ based on one's area of residence. Patient and patient family awareness about this issue is changing.

- As the number of elderly people increases, larger segments of the public are increasingly expecting to become centenarians, and more and more people will need to start considering how they want to live during late life stages. These considerations might lead to changes in medical and nursing-care services. It is a good time right now to take this opportunity for change to gather numerous and broad proposals for transforming medical and nursing care services, and to hold discussions on this matter.

Expectations of insurers

- The process of dividing roles between private and public insurers will undoubtedly continue in the future, and we are hopefully reaching the moment where serious discussions will commence on how the two groups can actually complement one another.
- Under the current system, while the risk of contracting a disease or suffering an injury varies based on the individual, risks associated with treatments after the individual becomes a patient do not vary that much from person to person. Considering these circumstances, it would be useful to consider adding an option to the existing public healthcare system that would allow for the payment of premiums to somehow ensure medical and nursing care service quality.

Contributions Japan could make to healthcare policymaking in other countries

- Ageing in Japan is proceeding at a rapid pace, but, at the same time, Japanese elderly people are in better health compared to elderly people in many other countries. The mechanisms and initiatives developed by Japan to encourage its citizens to maintain their health for a productive life even in their twilight years, and to guard against emergencies, could become extremely useful as references for other countries that are experiencing population ageing. By demonstrating how we were able to overcome various challenges, we could provide a great contribution to the world, as other countries look to us when developing their own policies on healthcare insurance.

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