



2. Process and players

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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

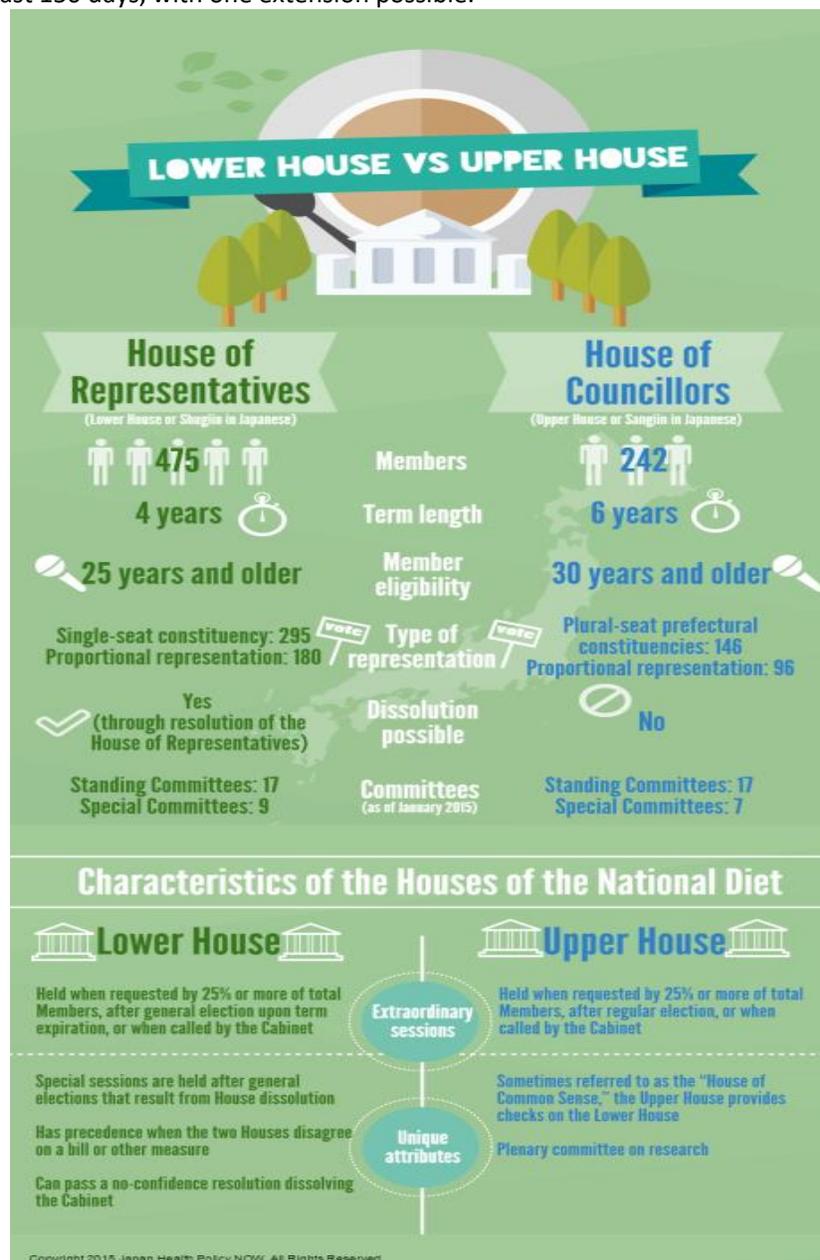
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2.1 Processes and players | Japan's government

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.¹ 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.²

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.³

<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").

¹ 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

² 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

³ 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.⁴

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.^{5,6}

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 discussions⁷

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.⁸

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.

⁴ Cabinet Legislation Bureau. How a bill becomes a law. (Accessed 30 January 2018) Retrieved from <http://www.clb.go.jp/law/index.html>

⁵ Cabinet Legislation Bureau. How a bill becomes a law. (Accessed 30 January 2018) Retrieved from <http://www.clb.go.jp/law/index.html>

⁶ Iwabuchi Yutaka (2013). Handbook of Japanese health policy formulation and structure. Chuohoki Publishing. p.32-41

⁷ Cabinet Office. Gathering of the deliberative council. (Accessed 30 January 2018) Retrieved from <http://www.cao.go.jp/council.html>

⁸ 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 bill⁹ (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).

⁹ 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.¹⁰ 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).¹¹

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 2001.¹² 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:¹³

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.

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

¹⁰ 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_iryuu/iryuuohoken/dl/shidou_kansa_01.pdf

¹¹ Pharmaceuticals and Medical Devices Agency. Outline of PMDA. (accessed 31 January 2018) Retrieved from <https://www.pmda.go.jp/files/000219906.pdf>

¹² Ministry of Health, Labour and Welfare. The beginnings of the Ministry of Health, Labour and Welfare

¹³ Ministry of Health, Labour and Welfare. Main work (Duties). (Accessed 31 January 2018) Retrieved from <http://www.mhlw.go.jp/kouseiroudoushou/shigoto/>

Pharmaceuticals and Medical Devices Agency (PMDA)

PMDA, established in 2004, is an independent administrative agency¹⁴, 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 2015.¹⁵

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.¹⁶

Ministry of Finance Budget Bureau

The Budget Bureau (BB) of the Ministry of Finance oversees 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.¹⁷

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

Some will say that if there is one term 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.

¹⁴ Pharmaceuticals and Medical Devices Agency. (PMDA) (accessed 11 October 2017) Retrieved from <https://www.pmda.go.jp/about-pmda/outline/0001.html>

¹⁵ 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>

¹⁶ 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>

¹⁷ 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/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.¹⁸ 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 Association¹⁹

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.²⁰

¹⁸Ikegami 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>

¹⁹ 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>

²⁰ 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.²¹

²¹ 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>