APPENDIX 3

Environmental Scan for Pan Canadian Pricing Alliance

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Australia
Ministry of Health's mission, vision and objectives

Australia's health care system is a partnership between the federal, state and territory governments. Through the Health and Ageing portfolio, the Australian Government works to provide a health care system to meet the health care and ageing needs of all Australians by providing national leadership, determining national policies and outcomes, improving programme management, research, regulation and working in partnership with state and territory governments, stakeholders and consumers.

The vision of the Department of Health and Ageing is of better health and active ageing for all Australians. The Department's priorities include to:

- support the Government in its reform of the health and hospital system;
- increase the focus of primary health care on people's needs and prevention/early intervention, to help reduce the incidence of chronic illness;
- improve the capacity of the health workforce through education and training and by expanding the roles of non-medical health professionals;
- improve the delivery of health care and early intervention measures for Indigenous Australians, to help close the gap in life expectancy rates between Indigenous and non-Indigenous Australians;
- support people living with mental illness, their families and their carers through integrated, effective and evidence-based mental health care;
- reconfigure health service delivery to achieve better health outcomes for people living in rural and remote communities; and support older Australians with a national health and ageing system responsive to their needs and improved governance arrangements and reforms.

Organization of health services and delivery systems

The organization of the public health system is strongly influenced by the federal system, where responsibility and funding for health is shared

between the Australian Government and the governments of the states and territories. The system is complex, with delivery provided by both the public and private sectors.

The Australian Government funds medical and pharmaceutical benefits, private health insurance subsidies, hearing services, and university training places for health workers, it shares responsibility with the states and territories for funding of public hospital services. The Australian Government also has a national leadership role in strategies to tackle significant health issues, as well as regulatory responsibilities. The state and territory governments provide public hospital services and community and public health services, assist with training of health workers through clinical training in public hospitals, and regulate private hospitals. Private practitioners provide most medical and dental services, as well as a range of allied health services.

The aim of the Australian health system is to give universal access to health care under what is known as 'Medicare', while allowing choice for individuals through substantial private sector involvement in delivery and financing. The three pillars of Medicare, funded by the Australian Government, are:

1. The Medicare Benefits Schedule — a universal programme that provides consumers with access to privately provided medical services and may include co-payments by users where the cost of services is not fully covered by the rebate
2. The Pharmaceutical Benefits Scheme — subsidization of a wide range of prescription medications supplied by community pharmacies.
3. Funding provided to states and territories to assist them in providing access to free public hospital services.

The Australian Government also funds a system of private health insurance rebates that subsidize the cost of premiums for private health insurers. Every Australian can elect to be treated as a private patient in a public hospital in order to have a choice of doctor. In addition, private hospitals provide an alternative to the public hospital system for many procedures. A large proportion of the health workforce is employed by the private sector, and corporatization is increasingly becoming a key organizing factor in the delivery of services such as general medicine, pathology and diagnostic imaging.

Australia has a well developed health technology assessment system to inform decisions about public and private health care funding for

pharmaceuticals and new medical technologies.

Health policy, planning and regulatory framework

The core values of the Australian health system are ensuring the affordability and accessibility of health care, as well as equitable access to necessary care, and reducing disparities in health outcomes. Providing consumers with choice in their health care is also a key principle of the system.

Since 2007, the Australian Government has embarked on a major process of reform in the health system.

In February 2011, at the Council of Australian Governments (COAG), the Commonwealth and all states and territories signed the Heads of Agreement on National Health Reform. The Heads of Agreement is the basis to negotiate a new National Health Reform Agreement, to be agreed by COAG.

Under the Heads of Agreement on National Health Reform, COAG has agreed to the establishment of a national approach to activity-based funding of public hospital services, to be funded, wherever possible, on the basis of a national efficient price for each public hospital service provided to public patients. An Independent Hospital Pricing Authority will be established to determine the efficient price of hospital services. A National Health Performance Authority will also be established to develop and produce reports on the performance of hospitals and health care services, including primary health care services. Under the agreement, the Commonwealth will increase its contribution to efficient growth funding for public hospitals to 45% from 1 July 2014, increasing to 50% from 1 July 2017.

All governments, federal, state and territory, will contribute funding for hospitals into a single national pool that will be administered by an independent national funding body. There will be complete transparency and visibility of government contributions into the pool and from the pool through state and territory accounts to Local Hospital Networks (LHNs), which will be responsible for the local governance and management of public hospitals. As well as amounts paid to LHNs, funds will flow from the pool to the states and territories for block funding for small regional and rural hospitals and to fund teaching, training and research undertaken in public hospitals.

Additionally, the Australian Commission on Safety and Quality in Health Care has been legislatively established as a permanent, independent authority to

develop, monitor and implement national standards for improving clinical safety and quality in hospitals and health care settings.

Supporting the reform package, the National Primary Health Care Strategy was released in May 2010. The strategy represents the first comprehensive national policy statement for primary health care in Australia and provides a road map to guide current and future policy and practice in the Australian primary health care sector. The National Preventative Health Strategy was also released in May 2010 and focuses on addressing the growing economic and health burden associated with obesity, tobacco and alcohol.

The Australian Government is taking action under the National Health Reform to build a national, secure e-health system. The Australian Government will provide funding of A$466.7 million (US$ 487.2 million) over two years from July 2010 to establish a personally controlled electronic health record system. Commencing in 2012-2013, consumers and their authorized health care providers will be able to securely access their own personally controlled e-health records via the Internet.

Health care financing

Currently, the Australian Government is the major funder of health services, while the state and territory governments have a major role in health service delivery. Medicare is a compulsory insurance system financed largely by general taxation revenue, some of which is raised by an income-related levy collected by the Australian Government.

In 2008-09, Australia's total expenditure on health goods and services amounted to A$113.5 billion (US$95.4 billion). Total health expenditure has been growing faster than the economy over the last decade, increasing from 7.8% of GDP in 1996-1997 to 9.0% of GDP in 2008-2009. Over two-thirds of total health expenditure is funded by the public sector; in 2008-2009, 69% of total health expenditure was funded by governments. The remaining one-third (31%) was funded by the private sector. Average annual real growth in total health expenditure over the decade to 2008-2009 was 5.5%. In 2008-2009, hospitals, medical services and medications were the three largest areas of health expenditure in the country, accounting for two-thirds of total health expenditure (public hospitals 29%, private hospitals 8%, medical services 17% and medications 13%)

China

Ministry of Health's mission, vision and objectives

The Health Care Reform Leading Group was established in 2006. It is currently composed of 20 ministries and chaired by Vice Premier Li Keqiang of the State Council, with the Ministers of Health and the National Development and Reform Commission (NDRC) as Vice-Chairs.

After three years of deliberation, in 2009, the Chinese Government announced its national health reform plan. The main objective is to provide universal health care coverage by 2020. Reforms are proposed in five areas: the public health system, the medical care delivery system, the health security system, the pharmaceutical system, and pilot hospital reform. The initial three-year implementation plan for 2009-2011 emphasizes several programmes, including improving the social health security system (urban employees, urban residents, rural cooperative medical services, and medical assistance programmes); establishing an essential medicines system; strengthening primary-level health care facilities; reducing disparities in public health care between regions; and piloting reforms in public hospital financing by reducing the reliance on drug sales for operational costs and salaries.

In 2009, the Government committed to spending 850 billion Yuan (US$ 124 billion) on fulfilling the three-year plan (est 0.8% annual increase in [2008] GDP), 39% from Central Government, although the total investment has increased to 1134.2 billion Yuan (US$ 177.8 billion) and the government investment to 365.9 billion Yuan (US$ 57.4 billion) . The Central Government allocation to implementing health reform in 2009 amounted to 118 billion Yuan, including 30.4 billion Yuan (US$ 4.4 billion) dedicated to insurance, 24.6 billion Yuan (US$ 3.6 billion) for public health and disease control, and 6.5 billion Yuan (US$ 2.4 billion) for construction . In 2010, 126.8 billion Yuan (US$ 19.9 billion) was allocated to implement the health reform.

After two years of implementation, the Government has announced a series of achievements by end of 2010, including:

- The new rural cooperative medical system: 96% of the rural population (836 million people) covered by health insurance.
- The pharmaceutical system: about 86% of government-run primary-level health care facilities adopting the essential medicines

list.

- The public health system: 30 million children aged below 15 receiving free hepatitis B vaccine, 8.85 million rural women subsidized for hospital delivery, 473 thousand million rural women screened for breast cancer, 4.89 million rural women screened for cervical carcinoma.
- Primary-level health care: 32 700 township health centres, 37 800 urban community health centres and 648 400 village clinics built.
- The public hospital reforms pilot: 16 national-level and 31 provincial-level pilot cities have carried out public hospital reforms; and nearly 100 hospitals in 22 provinces have launched an electronic medical record (EMR) pilot test.

There are many targets for 2011. They include: maintaining 90% or higher health insurance coverage for both urban and rural areas; increasing to 200 Yuan the per person government subsidy to urban residents' basic medical insurance and new rural cooperative health insurance; and rebuilding 300 county hospitals, 1000 township health centres and 13000 community health stations.

Organization of health services and delivery systems

Since 2003, dramatic increases in insurance coverage have been accompanied by increased service utilization, particularly in rural areas. Between 2003 and 2011, national insurance coverage increased from 23.1% to 90%. By the end of 2010, the participation rate for the rural cooperative medical system had reached 96%.

Changes in health financing have also led to changes in utilization patterns. Increasing rates of Caesarean section, particularly in urban areas, and frequent use of injections and infusions in primary care settings illustrate the unnecessary use of certain treatment measures. Cesarean section rates have increased overall from 16.3% to 26.8%, and urban rates were 50.9% in 2008. An assessment of 121 471 prescriptions for patients diagnosed with a non-communicable condition in 218 primary care facilities was conducted as part of the National Health Services Survey (NHSS) 2008. In village clinics and township health centers, 66% and 61% of patients were prescribed antibiotics, respectively. Intramuscular and intravenous injection rates were also very high at 30% and 35% of rural prescriptions, respectively, and 13% and 32% of urban prescriptions, respectively. These high figures correspond to other smaller-scale studies conducted in China. Such treatment patterns are striking given the prevalence of non-

communicable disease treatment.

While health insurance coverage is increasing, especially in rural areas, many people are underinsured and continue to face high out-of-pocket costs, with such costs accounting for 41.1% of total health expenditure until 2009.

Households continue to face financial barriers in accessing health care, and household health expenditures remain high: 17.4% of patients failed to be hospitalized after referral for financial reasons in 2008, a decline from 21.8% in 2003. An increase was seen in the percentage of households with catastrophic expenses (5.0% to 5.6%), although fewer households became impoverished because of medical care (6.1% to 4.8%) between 2003 and 2008.

Employee health insurance, medical insurance for urban residents and rural cooperative medical and hospitalization cost insurance have increased their reimbursement levels to approximately 75%, 60% and 70% respectively. Benefits are not portable across regions, however, which is a concern for migrant populations and migrant workers. In 2009, one estimate suggested that 48.7% of migrant populations were participating in health insurance. However, issues remain in identifying migrant populations and accurately measuring their numbers and movements.

While major progress has been observed in expansion of rural insurance schemes and in some indicators of service use and expenditures, gaps remain between the poorest and better-off and, for some indicators, between eastern, central and western China. National Health Services Survey data show the need for policies to promote equitable access and risk protection, particularly for the urban and rural poor. The current health reform investments should be monitored closely to determine their impact on trends in service utilization, health-seeking behaviour, quality of care, risk protection and, ultimately, health.

Since expenditure on medicines remains an important component of out-of-pocket expenditure, increasing the availability and affordability of generic essential medicines is an important policy. The Government is in the process of outlining reforms to improve access to quality, safe essential medicines, modifying the pricing system and strengthening medicine production and distribution systems.

Health policy, planning and regulatory framework

A major component of the health reforms aims to better define government

roles in the health sector. Important efforts have been made to reduce ambiguity and redundancy in responsibilities, as well as the competing interests among departments and in government roles in health across agencies.

Regulations relating to public health and health care delivery systems are underdeveloped and poorly enforced, and monitoring capacity is weak. Most health facilities lack clinical governance systems, and important gaps exist in the regulatory system to ensure the quality of care. Deficiencies in clinical quality have resulted from financial incentives in the delivery system, combined with difficulties in: posting qualified human resources to peripheral facilities, gaining sufficient government resource allocation, and the supervision and regulatory systems for the delivery systems. Safety standards and health regulations, as well as their enforcement, could be strengthened, particularly in rural areas. With the implementation of the health reform in 2009, the Ministry of Health established the National Center for Health Quality Management and Control, which aims to designate and guide regional centres in strengthening health quality management. Performance evaluation also focuses on quality evaluation, as a main part of public hospital reform.

The overwhelming majority of the Chinese population seeks out traditional Chinese medicine (TCM) to address their health problems. The Government promotes the development of a modern TCM industry, as well as the integration of TCM into the national health care system and integrated training of health care practitioners. In 2009, the State Administration of Traditional Chinese Medicine (SATCM) implemented TCM Hospital Management Year actions in order to highlight the special advantage of TCM, strengthen its management in terms of quality and safety, and improve quality, safety and efficiency. In 2010, the Minister of Health identified several key priorities for TCM development, including increasing policy support for TCM; strengthening research on key TCM issues and building capacity for TCM research; establishing well-known TCM hospitals and departments; promoting a culture of TCM; and strengthening international cooperation and communication on TCM. In addition, the Ministry of Health intends to promote TCM legislation and standardization, as well as innovation in the field, in 2011.

However, a number of challenges to further development of TCM remain. There is a lack of unified, systematic regulations to assess the safety and

efficacy and ensure the quality of TCM products. In addition, there are no national TCM standards or guidelines for TCM clinical trials, and evidenced-based TCM product testing and research are still needed. In view of the vast differences in the qualifications of TCM practitioners, the quality of TCM education needs to be strengthened, and the management and supervision of TCM institutions need to be regulated.

Health care financing

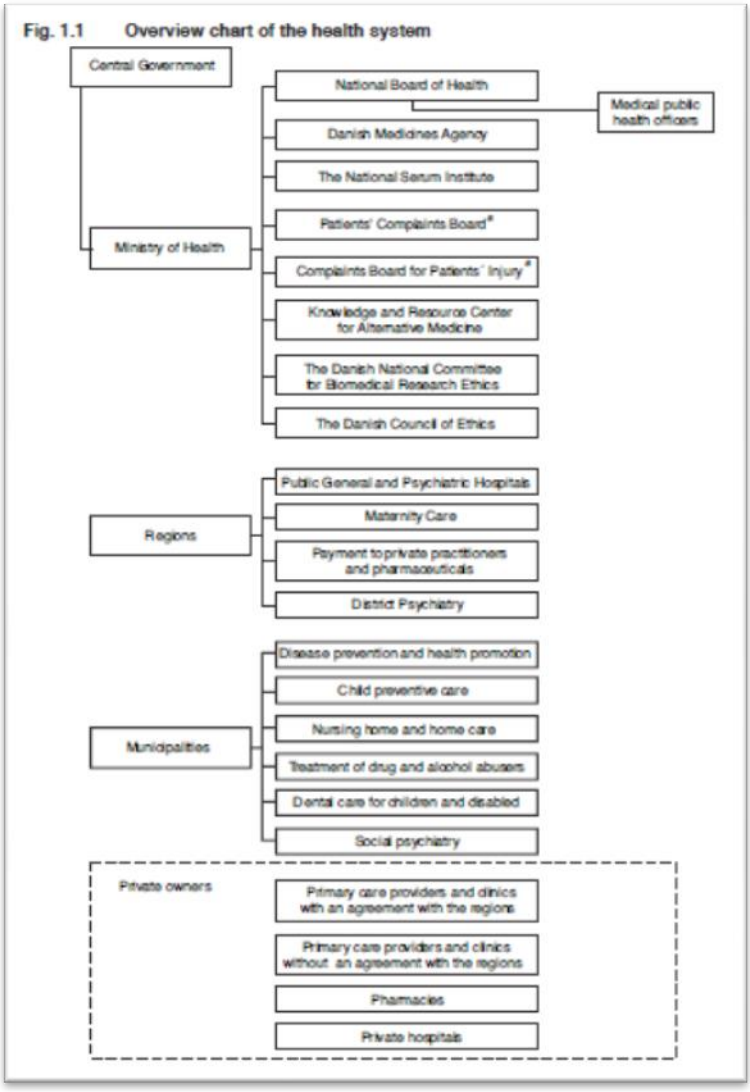
Total health expenditures rose from 3% of GDP in 1978 to 4.6% of GDP, or US$ 168.7 per person in 2009. Of that total, the Government contributed 50.3% and private expenditure 41.1%. The contribution from public financing has increased and the proportion coming from personal health spending has fallen, leading to a reduction in the burden of difficulty associated with getting medical services and an increase in the satisfaction levels of both urban and rural residents.

Public resource allocation is highly decentralized. Under the current health system, local health departments and other health care providers are expected to generate a significant share of their own operating budgets, with township, county, prefecture and provincial governments administering about 90% of all government spending on health. While localities are given the responsibility to finance health care, however, local governments are unable to raise revenue through taxes to finance basic public services, especially in resource-poor communities. This provides an incentive to focus on more profitable curative care and medicines to generate larger profit margins. Government spending on health tends to be lower in provinces with higher numbers of rural poor. Thus, poor localities have access to fewer and lower quality services for public health. The health reform plan aims to resolve the problem by increasing public spending on basic health services, as well as reducing the reliance on medicines and service sales to fund facility operating costs. The Government is committed to spending 25 Yuan (US$ 3.9) per person on a basic public health package. Central government allocation of resources for the public health package varies according to local economic development capacity.

Denmark

Overview of the health system

The defining feature of the Danish health system is decentralized responsibility for primary and secondary health care, as illustrated in Fig. 1.1.



At the state level the Ministry of Health has a governing role over municipal organization and management, as well as the supervision and partial financing of the municipalities and regions. In the field of health care, the Ministry is in charge of the administrative functions that are related to the organization and financing of the health system, psychiatry and health insurance as well as the market authorization of pharmaceuticals and supervision of the pharmacy sector. Prevention and health promotion are also part of the Ministry's remit. Figure 1.1 provides further details of the Ministry's responsibilities.

The regions own and run hospitals, and partly or fully finance private practitioners such as general practitioners (GPs), specialists, chiropractors and physiotherapists. They also provide reimbursement for pharmaceutical care.

At the local level, the municipalities are responsible for disease prevention, health promotion and rehabilitation outside hospitals, as well as other areas of health care, as illustrated in Fig. 1.1. For an expanded description of the structure of the health system, see Section “Organizational overview”.

Organizational overview

The defining feature of the Danish health system is its decentralized responsibility for primary and secondary health care. However, important negotiation and coordination channels exist between the State, regions and municipalities, and the political focus on controlling health care costs has encouraged a trend towards more formal cooperation. See Fig. 2.1 for an overview of the organization of the system.

State level

Responsibility for preparing legislation and providing overall guidelines for the health sector lies with the Ministry of Health. Each year the Ministry of Health, the Ministry of Finance and the regional and municipal councils – represented by the Danish Regions and the National Association of Local Authorities – take part in a national budget negotiation to set targets for health care expenditure. These targets are not legally binding. The National Board of Health, a central body established in 1803 and now connected to the Ministry of Health, is responsible for supervising health personnel and institutions, and for advising different ministries, regions and municipalities

on health issues.

Regional level
The five regions are governed by councils, which are elected every four years. They are financed by the State and the municipalities. The regions own and run hospitals and prenatal care centres, and they also finance GPs, specialists, physiotherapists, dentists and pharmaceuticals. Reimbursements for private practitioners and salaries for employed health professionals are agreed through negotiations between the Danish Regions and the different professional organizations. The Ministry of Health, the Ministry of Finance and the National Association of Local Authorities also participate in these negotiations.

Municipal level
The 98 municipalities are also governed by councils elected every four years (at the same time as regional council elections). They are responsible for providing services such as nursing homes, home nurses, health visitors, municipal dentists, prevention and health promotion, and institutions for people with special needs (i.e. people with disabilities, treatment for drug- and alcohol-related problems and school health services). These activities are financed by taxes, with funds distributed through global budgets, and carried out by salaried health professionals. Salaries and working conditions are negotiated by the National Association of Local Authorities and the different professional organizations.

Planning, regulation and management

Policy development takes place at central, regional and local levels. The 2007 reform implies a more important role for the central level. With the reform, the influence of the National Board of Health on hospital planning was strengthened with the purpose of ensuring more equal treatment across the country. Implementation of policies and provision of services still take place at the regional and local levels.

The National Board of Health has an advisory function over the political bodies at all levels, and it has a supervisory function over all authorized health professionals and institutions, except practitioners of complementary and alternative medicine (CAM). The Parliament and the Government, with few exceptions, outline the general policies, and make decisions on the overall organizational structure, financial framework of activities and responsibilities of the health care sector.

Most health care institutions, hospitals, nursing homes and school health clinics are owned and managed by the regions or municipalities. GPs, specialists, dentists and physiotherapists are self-employed and reimbursed by the regions

based on taxation. Pharmacies are privately owned but strictly regulated, and pharmaceuticals are subsidized by the regions.

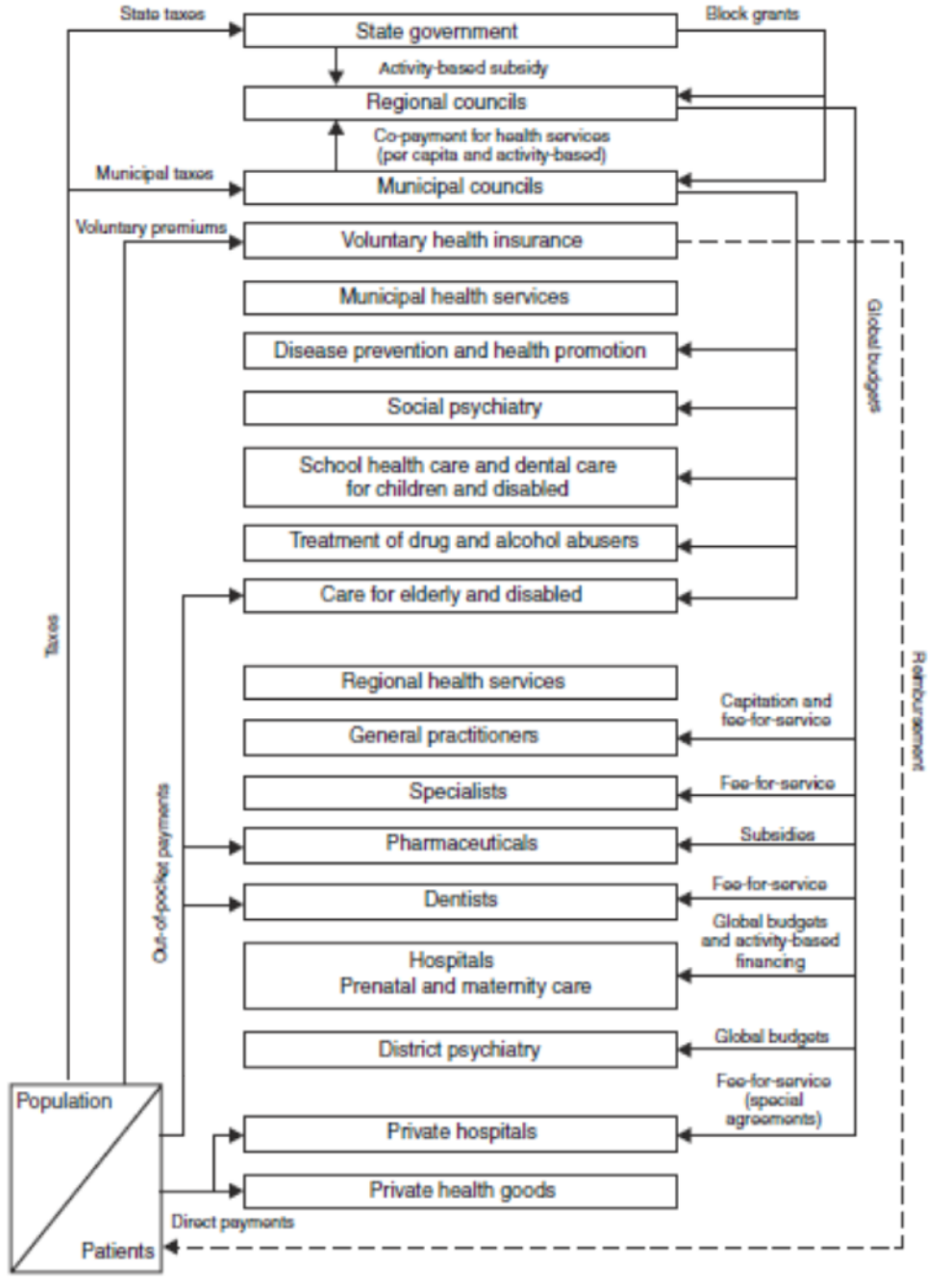
Financial resources

The Danish health system is mainly financed by state and municipal taxes. Other sources of finance include user charges for some health goods and services and VHI, which is taken out to partially cover user charges.
Figure 4.1 gives an overview of the system's financing arrangements. The most significant resource allocation mechanisms are listed here.

- National level: the national budget negotiation takes place once a year between the Ministry of Health, the Ministry of Finance and the regional and municipal councils, which are represented by the Danish Regions and the National Association of Local Authorities.
- Regional/local level: political budget negotiations take place within the regional and municipal councils within nationally specified ceilings.

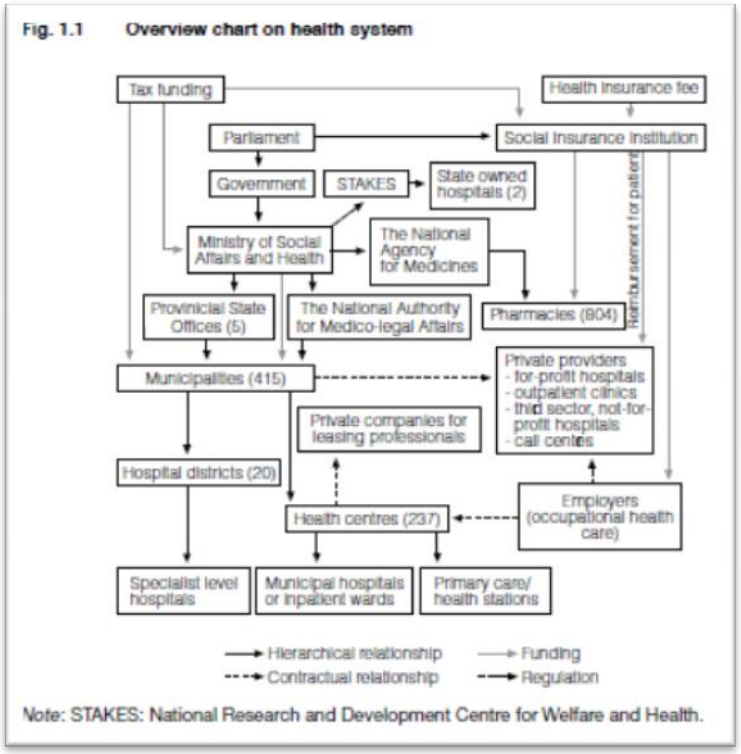
In 2003, the total health expenditure per capita was US$ 2763 in purchasing power parity (PPP), of which 83% was public expenditure. The main portion of health-related public expenditure is spent on hospitals. The average growth rate of the total expenditure on health between 1998 and 2003 was 2.8%. Total health expenditure as a percentage of GDP has risen moderately during the period 1995–2003, corresponding to an average yearly increase of 0.1%. This rise was preceded by a decline in total health expenditure as a percentage of GDP during the period 1980–1995. The public proportion of total health expenditure was fairly stable between 1995 and 2003.

Fig. 4.1 Financing flow chart



Finland
Overview of the health system

In practice in Finland there are three different health care systems which receive public funding: municipal health care, private health care and occupational health care (Fig. 1.1). Usually, employed persons have the possibility to choose between these. According to a population survey, about 45% of physician visits of employed people were in occupational health care, 35% in municipal health care and 15% in private health care. For low-income unemployed people the municipal health care system is, in practice, the only choice. There are significant differences between the systems, for example in the scope of services, user-fees and waiting times.



There are also different public financing mechanisms for health care services in Finland: municipal financing based on taxes and National Health Insurance (NHI) financing based on compulsory insurance fees (this is henceforth referred to as “dual financing”). Municipalities fund municipal health care services (except outpatient drugs and transport costs) and NHI funds, for example, private health care, occupational health care, outpatient drugs, transport costs and sickness allowance.

The largest share of health care services is provided by the municipal health

care system (71% of outpatient physician visits, 59% of outpatient dentist visits and 95% of inpatient care periods). In 2008 there were 415 municipalities in Finland, with a median number of inhabitants of 5000. Municipal health care services are financed by municipal taxes, state subsidies and user-fees.

All municipalities are, by law (Primary Health Care Act), obliged to maintain health centres for the provision of primary health care services, either on their own or jointly through a local federation of municipalities. There were 237 health centres in Finland in 2007 (excluding Åland Islands). Practically all health centres have general practitioner (GP)-run inpatient units or an arrangement for using such beds in a nearby health centre. Municipalities with their own health centres usually use prospective budgets. In federation-owned health centres the budgets are built in a similar way but the sharing of costs between member municipalities is usually determined by the volume of services given. Physicians in health centres are usually salaried employees of the municipalities. The payment system of GPs in municipal health centres varies.

Specialist level care in the municipal health care system is provided by 20 hospital districts. Each municipality must belong as a member to one of the hospital districts (Act on Specialized Medical Care). Each hospital district has one or several hospitals, of which one is a central hospital. The hospital district organizes and provides specialist medical services for the population of their member municipalities. Hospital districts are managed and funded by the member municipalities. Hospital districts have varied methods for collecting funding. The majority of funding collected is based on actual clinical services used. The population base of hospital districts varies from 65 000 to 1.4 million.

Municipalities can also purchase health care services (primary health care services or specialized health care services) from other municipalities, other hospital districts, private providers or from the third sector.
The Åland Islands are an autonomous Swedish-speaking region with 16 municipalities and 26 000 inhabitants. The Åland Government is responsible for providing health care services in the region. Services which are not provided in the region are purchased from Finland or Sweden.

Seventeen per cent of the total cost of health care in Finland is financed by the statutory NHI scheme. The scheme is run by the Social Insurance Institution (SII, Finnish acronym KELA), with about 260 local offices throughout the country. SII falls under the authority of Parliament. The main funding to NHI comes from the state budget (28% in 2006), the insured (33%) and employees (38%).

NHI covers part of outpatient drug costs, part of medical costs in the private sector, part of the costs of occupational health care, compensation of travel costs to health care units, sickness allowance and maternity leave allowance. Of services funded by public sources (municipalities and NHI), about 16% of outpatient visits to physicians, 41% of outpatient visits to dentists and 5% of inpatient care periods are provided by the private sector.

Employers are obliged to provide preventive occupational health care for their employees (under the Occupational Health Care Act). As part of occupational health care, many large- or medium-sized employers also provide curative outpatient services (13% of outpatient physician visits are provided by the occupational health care system). Occupational health services can be provided by the employer itself or the employer can purchase them from another employer (42% of expenses in 2004), or from the municipal health centres (16% of expenses), from private health care providers (29% of expenses) or from other sources (12% of expenses). The NHI scheme covers about 40% of the expenses.

Pharmacies are mainly privately owned by pharmacists. There were 804 pharmacies in Finland in 2006 (NAM 2007). They are regulated in several ways: their margins and prices are fixed by the Government, they cannot be owned by companies, and the National Agency of Medicines (NAM) decides in which locations pharmacies are placed and who runs them. Outpatient drugs are partly reimbursed by NHI. These reimbursements are paid mainly directly to pharmacies.

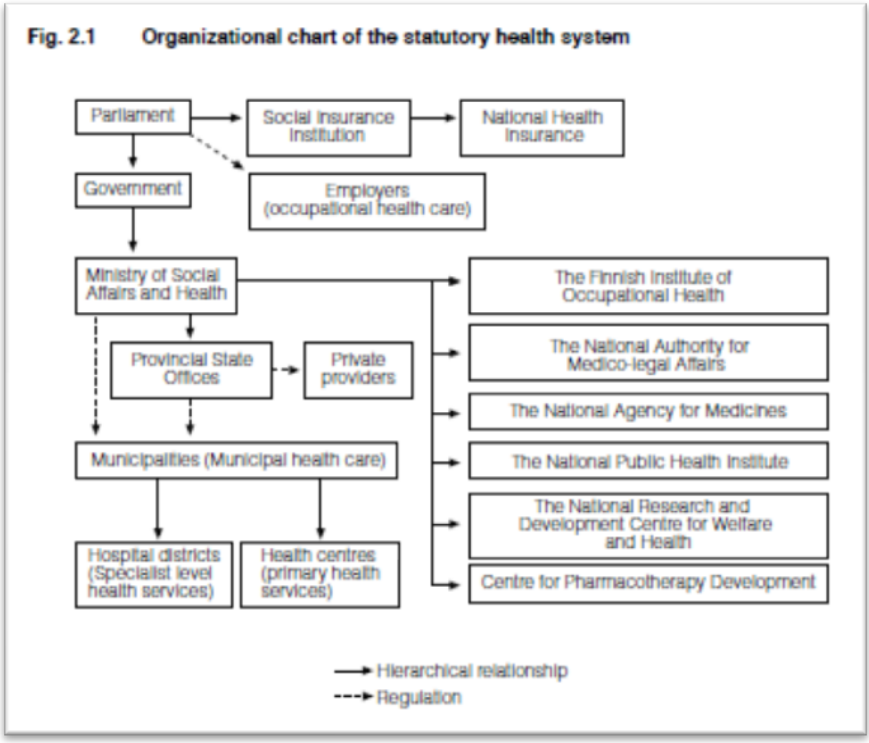
The Ministry of Social Affairs and Health (MSAH) directs and guides social and health services at the national level. It defines general social and health policy, prepares major reforms and proposals for legislation, monitors their implementation and assists the Government in decision-making. The Government decides on general national priorities and proposes bills to be discussed by the Parliament. The lower level of state administration comprises five provinces plus the autonomous Åland Islands. The provincial state offices promote national and regional objectives of the central administration, and keep contacts with municipalities in their area. Their social and health departments are responsible for, among other things, guiding and supervising both municipal and private health care providers.

Organizational overview

In practice, in Finland there are three different health care systems which

receive public funding: municipal health care funded by taxes, private health care partly funded by NHI and occupational health care partly funded by NHI (Fig. 2.1). The role of the state is to steer the health care system at a general level mainly by legislation and financing. The provision of private health care is rather weakly regulated by the state.

Fig. 2.1 Organizational chart of the statutory health system



Municipalities

Municipalities (i.e. the local authorities) have, by law, the main responsibility for ensuring basic services such as education (except university education) and social and health services are provided for their inhabitants. Currently there are 415 municipalities (in 2008). The number of municipalities has decreased in the last five years from 448. The population of municipalities (outside of Åland Islands) currently varies from 250 inhabitants to 560 000 (the smallest municipality, Velkua, will merge with neighbouring municipalities on 1 January 2009). The mean size is about 13 000 inhabitants and the median about 5 000 inhabitants. Municipalities have the right to levy income and real estate taxes. They also receive a subsidy from the state to enable them to organize the services they are obliged to provide. In addition to the state subsidy for health care, they receive state subsidies for social services and schooling. The state subsidy to municipal social welfare and health care expenditure is determined by the population, age structure and morbidity in the municipality plus a number

of other computational factors. The subsidies constitute about 25% to 30% of municipal spending on health services.

The main decision-making power in municipalities lies with the municipal council, which is elected every four years by the inhabitants of the municipality. The council appoints a municipal executive board, which is accountable to the council. The council also appoints members to the various municipal committees, according to the relative strength of political parties in the municipal council (every political party is granted the same proportion of the seats in a committee as it has in the council). The committees usually comprise those for health, social services, education, technical infrastructure and a number of others, and are appointed for four years. The municipal council, the municipal executive board and the committees are politically accountable to the inhabitants of the municipality. In addition, the municipal manager and a varying number of officials work in the administration of the municipalities.

There are variations in detail and emphasis in the decision-making process in municipalities. The general trend has been towards delegating power from municipal councils to the various committees and leading officials. Decisions on the planning and organization of health care are made by the health committee, the municipal council and the municipal executive board. Here again there are variations. The leading persons of the municipal health centres are often also included in the planning and organization of health services. To improve the coordination of social and health services, the traditionally separate health boards and social welfare and services boards have been merged into a single board in most municipalities. In principle, the fact that social and health services are both organized and funded by the municipalities holds great potential for good coordination and integration of services, particularly for vulnerable groups (for example older people, people with mental health problems, and people with alcohol or drug abuse problems), but this potential has not always been fully exploited in practice.

Primary health services provided by municipalities are defined in the Primary Health Care Act. The act states that every municipality must have a health centre which provides primary health services. Municipalities can either provide these services independently or join with neighbouring municipalities in joint municipal boards which set up a joint health centre (a municipal federation-maintained health centre). There were 237 health centres in Finland (excluding Åland Islands), of which 58 were joint health centres in 2007. In larger cities, the services of health centres are provided through several health stations located in different parts of the city (for example Helsinki has 29

health stations around the city). Municipalities can also purchase some primary health services from private providers or hospital districts. Health centres provide occupational health care services for those employers who choose to purchase these services from health centres.

About 86% of health centres also had inpatient wards in 2003. In 2006 there were 24.9 million outpatient visits to health centres and 7.3 million care days in inpatient wards. Of all visits, 36% were to physicians and the rest were to other professionals such as nurses, public health nurses, midwives, physiotherapists and psychologists. Of all outpatient visits, 9% were to maternity and child welfare clinics, 15% were home nursing visits and 5% to occupational health care. In oral health care there were 4.9 million visits of which 79% were visits to dentists.

Specialized care funded by municipalities is mainly provided by hospitals maintained by the hospital districts and regulated by the Act on Specialized Medical Care. Currently, the Act divides the country into 20 hospital districts (excluding Åland Islands). Each municipality must be a member of one hospital district (the number of member municipalities varies from 6 to 58). The hospital districts organize and provide specialist medical services for the population of their member municipalities. The hospital districts are federations of municipalities. These federations are separate from federations maintaining health centres. However, recently there have been local reforms to integrate these two organizations.

Each hospital district has a central hospital, five of which are university-level teaching hospitals. Hospital districts are managed and funded by the member municipalities. The catchment population of hospital districts varies from 65 000 to 1.4 million inhabitants. A referral from a licensed physician is needed for access to medical care provided at the hospital districts. Life-threatening emergencies are of course exempt from this requirement. The referring physician does not have to work in the municipal health centre and can be, for example, a private physician.

Supreme decision-making power in hospital districts is exercised by the hospital district council, whose term of office is the period between municipal elections, i.e. four years. Each municipality has one to six seats in the council depending on the size of their population. Each municipality's share of votes is the same as its share of total population within the district (but it cannot be more than one fifth of all votes). Practical administration is directed by the executive board elected by the council. Usually members of both the council and the executive board are local politicians and the composition of representatives of political parties reflects the support

received by the political parties in municipal elections. The council adopts the annual budget, approves financial statements and makes decisions on major investments. The emphasis of the executive board is on strategic goals, coordination of activities, employer duties and administrative steering.

The council meets twice a year, while the board generally meets monthly. The executive management consists of two to six permanently appointed officials (for example, the hospital district director, a medical director and a nursing director).

There are different contractual or negotiation mechanisms between hospital districts and municipalities for agreeing on target volumes and payments which comprise elements of purchaser and provider separation, although ultimately the relationship is hierarchical and municipalities cover any deficits and retain any savings in their accounts.

National level

The Government decides on general national strategies and priorities and proposes bills to be discussed by Parliament. Health care policy is primarily the field of the MSAH. The MSAH directs and guides the development and policies of social protection, social welfare and health care. It defines the main course of social and health policy, prepares legislation and key reforms and steers their implementation, and handles the necessary links with the political decision-making process. The general aims of social welfare and health care and the measures that will be taken in order to fulfil these aims are adopted in the National Development Programme for Social and Welfare (previously Target and Action Plan for Social Welfare and Health Care) that is drawn up for the whole period of office of each Government, normally for four years.

The ministry's work is led by two ministers: the Minister of Social Affairs and Health and the Minister of Health and Social Services. The ministry is divided into six departments: the Administrative Department, the Insurance Department, the Department for Family and Social Affairs, the Health Department, the Finance and Planning Department and the Department for Occupational Health & Safety. The Health Department is responsible for the development and steering of health promotion and disease prevention, health care services at all levels, occupational health services, pharmaceutical policies (except pricing) and environmental health, as well as for the drafting of legislation and budgeting regarding these areas.

The Insurance Department is responsible for NHI among other things.

The Pharmaceutical Pricing Board (PPB), which approves reasonable prices and the reimbursement status of pharmaceuticals, is also in this department. Decision-making is based on the applications of pharmaceutical companies.

Given the scope and volume of policies and programme, legislation and budgeting handled by the MSAH, its staff is relatively small. The Health Department, for instance, contains little over 70 staff. This is explained by the fact that the ministry relies on the extensive use of a well-functioning system of expert organizations and advisory bodies. The agencies and institutions subordinate to the MSAH are responsible for various issues related to social welfare and health care in Finland:

- The STAKES (about 500 employees) monitors and evaluates activities in social welfare and health care services, and carries out research and development work in these fields.
- The NAMLA (about 70 employees) guides and supervises the provision of health services in Finland. It also undertakes activities related to the registration of health care professionals, forensic psychiatry and licensing.
- The NAM (about 200 employees) maintains and promotes the safe use of medicines, medical devices and blood products. It grants permissions for the sales of pharmaceutical products and assesses the quality and other documentation related to market authorization of medical products. It also supervises the manufacture, import and distribution of medicines and disseminates information on pharmaceuticals (see section 6.6).
- The National Public Health Institute (KTL) (about 900 employees) carries out research on diseases and their prevention, collects data on communicable diseases, health behaviour and the effects of health promotion, and ensures the availability of vaccines in the country.
- The Radiation and Nuclear Safety Authority (about 340 employees) sets the regulations for the use of radiation and nuclear energy and supervises implementation of the regulations. It is also an expert institute that carries out research on radiation and its effects, determines risks caused by radiation and monitors the radiation safety of the Finnish environment.
- The National Product Control Agency for Welfare and Health (about 90 employees) handles the administration of licensing connected with the import, manufacture and sales of alcoholic beverages and tobacco products. It is also responsible for reports and other tasks as required by the Chemicals and Pesticides Act.

- The Finnish Institute of Occupational Health (FIOH) (about 800 employees) carries out research, offers training for occupational health and safety professionals, provides advisory services and disseminates information on occupational health.
- The Centre for Pharmacotherapy Development (Rohto) (about 10 employees) promotes rational drug use by gathering and distributing information on pharmacotherapy and promoting its use in clinical practice. This agency is still relatively small, having been founded only in 2003.
- The state has two psychiatric hospitals (mainly for forensic psychiatry). They are managed through STAKES. In addition the state operates special hospitals for military forces and prisoners.

The Ministry of Employment and the Economy is also quite active in the field of health care, mainly from a commercial and business promotion perspective. For example, it governs the National Technology Agency of Finland (TEKES) which runs the Healthcare Technology Programme. The programme has the objective of improving the quality and profitability of health care related industries, and promoting business activities and export (the value of the programme is 150 million euros). The ministry also governs the Finnish Competition Authority whose objective it is to protect sound and effective economic competition and to increase economic efficiency in both private and public-sector activity.

The Ministry of Education is responsible for planning and subsidizing the education and training of health personnel as well as research.

There is a further administrative level between the state and municipalities, the province. Since 1997 there have been five provinces (excluding the Åland Islands) in the country. The provincial administration is part of the state administration and promotes national and regional objectives. Each province has its own provincial state office with several departments, including a social and health department. The social and health departments are responsible for guiding and supervising both public and private health care as well as assessing basic services in municipalities. Their responsibilities also include the handling of appeals relating to health service provision. They also support and participate in various training and development activities in their respective provinces.

Finland has eight Occupational Health and Safety Inspectorates. These are supervisory authorities within the state regional administration with

responsibility for creating the necessary prerequisites for healthy and safe working conditions that promote working capacity. The Inspectorates report on related development needs to the Department for Occupational Health and Safety within the MSAH.

The organizational structures of state governance in health and social services at a central and provincial level, including the research and development institutions, are currently under review. The Government is expected to decide on proposals during 2008.

National Health Insurance and the private sector

The statutory NHI scheme finances 17% of the total costs of health care. The scheme is run by the SII, with about 260 local offices all over the country. SII falls under the authority of the Parliament. NHI covers all Finnish residents and it includes outpatient drug reimbursement, reimbursement of medical costs in the private sector, compensation of travel costs to health care units, sickness allowance, maternity leave allowance and compensation for some rehabilitation services (for co-payments see sections 3.3.3.2 and 3.3.3.3). In addition, NHI reimburses part of the costs of occupational health care. NHI is funded by employers (33% in 2006), the insured (38%) and the state (28%). The insured pay income-based insurance fees which are collected in connection with taxation (between 1.91% and 2.08% in 2008). The Private Health Care Act regulates the provision of private health services. The NHI scheme covers part of private health care costs (about one third, depending on the type of care). Private service providers can price services freely, but reimbursements are fixed (see sections 3.2.2.3 and 3.3.3.2). In terms of number of units, the most common private health care providers in Finland are physiotherapy units made up of 2–3 workers (about 1500 units in 2005) and medical doctors' practices (about 1100). The largest provider units, a few hospitals and occupational health care units have several hundred employees. In 2006 there were 16 000 working age physicians in Finland, of which 1700 worked full-time as private physicians and 30% were employed in the public sector but held a private practice outside their regular working hours for an average of four hours per week ("dual practice") (Suomen Lääkäriliitto 2006).

Private health care in Finland mainly comprises ambulatory care, available mostly in the large cities. In 2006 there were 3.5 million outpatient visits to private doctors (compensated by NHI), of which 79% were visits to specialists (SII 2007a). In terms of the number of outpatient visits, the most important fields of specialty in private health care were gynaecology and ophthalmology (together comprising more than one third of visits to specialists). Private services

funded by NHI comprised about 16% of total outpatient GP and specialist visits in 2005. Private hospitals produced 71 700 inpatient care periods in 2005 which comprised about 5% of all inpatient care periods in Finland. About 36% of private sector outpatient visits are provided in the region surrounding the capital.

Nongovernmental organizations (NGOs) and foundations are active in the health care sector. These organizations provide a very broad spectrum of services. Municipalities and hospital districts can purchase services from these providers. These organizations can receive subsidies from the Finnish Slot Machine Association (which has a monopoly on gambling in Finland and is governed by the state) for providing health care services. There is also a special foundation (Finnish Student Health Service) which provides ambulatory health care to university students. This organization is partly funded by the NHI scheme.

Occupational health care

The Occupational Health Care Act enacted in 1979 obliges employers to provide occupational health care for their employees. The Act defines compulsory occupational health care as those health services that are necessary to prevent health risks caused by work. NHI reimburses employers 50% of the necessary and appropriate costs of occupational health care (maximum reimbursement is about 60 euros per employee per year for compulsory services and about 90 euros for voluntary services). Employers and employees participate in financing the scheme through their NHI payments.

In 2004, about 84% of all employees in Finland were offered occupational health care by their employers (SII 2007b). Some small employers did not organize health care services for employees or did not apply for reimbursement from NHI. About 13% of outpatient visits to physicians are provided by occupational health care. In 2004, employers purchased or provided 409 million euros worth of occupational health services and were subsidized 177 million euros (43%) for this from NHI.

Employers can supplement compulsory occupational health care by voluntarily organizing further medical services. Employers are free to decide the scope of these voluntary services. About 90% of employees receiving compulsory occupational health care also received voluntary services. Employees are not charged for using these services (but limits to services available are set by the employer). Sixty-one per cent of employers' total expenditure was for voluntary services (these figures only include expenses which employers declared to NHI).

Occupational health services can be provided by the employer itself, jointly with other employers or the employer can purchase them from another employer (in total accounting for 42% of occupational health expenses in 2004), or the employer can purchase services from municipal health centres (16% of expenses), from private health care providers (29% of expenses) or from other sources (12% of expenses).

Because of the occupational health care system, the majority of the working population effectively has "double" coverage for primary care (i.e. care in both municipal health centres and occupational health services). Also, since private primary care is subsidized by the state, some have "triple" coverage.

Other organizations

Pharmacies are privately owned by pharmacists. There were 804 private pharmacies in Finland in 2006 including subsidiary pharmacies (NAM 2007). In addition to this, the University of Helsinki and the University of Kuopio have a special right to own pharmacies (in total 18 pharmacies). The Finnish Slot Machine Association has become quite an important financier of non-profit voluntary organizations in the health and social welfare sector. Annually, it gives around 300 million euros to support NGO work promoting health and social well-being. The association is governed by the state together with major NGOs related to social welfare and health. It operates slot machines, amusement machines and casino games in which it has a monopoly imposed by the state. A government decree regulates the administrative structure of the association and an act regulates the distribution of funds. The final decision on funding is made by the Government. The objective of the funding activities is to promote the health and social welfare of people in Finland. Groups targeted include, for example, older and disabled people, young families, people with chronic diseases and substance abusers. The association only supports third-sector organizations; it does not finance any municipal health services or private profit-making providers.

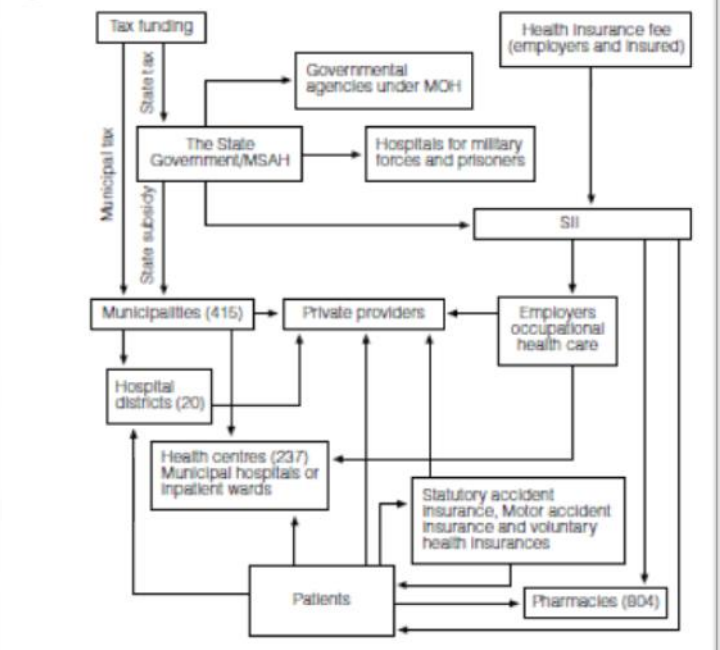
Finland has a large number of patient organizations. It is estimated that there are about 130–150 national patient organizations with budgets up to 58 million euros. The main functions of these organizations are information dissemination, supporting patients, lobbying, producing services and supporting research. One major source of their funding is the Finnish Slot Machine Association. Other important public funding sources are the MSAH, the SSI and municipalities.

All health care professionals have their own trade unions, for example the Finnish Medical Association for physicians, the Finnish Dental Association for dentists, the Finnish Pharmacists' Association for professionals in the field of pharmacy, and the Union of Health and Social Care Professionals for nurses, midwives, dental assistants, medical laboratory technicians, radiographers, mental health nurses, emergency medical technicians and ambulance staff. In addition to trade unions there are many other active professional organizations. Perhaps the most important of these is a medical scientific organization, the Finnish Medical Society, Duodecim, which produces national Current Care Guidelines (see section 7.1.1.6), organizes consensus meetings about important topics in health care, maintains a comprehensive Evidence-based medicine (EBM) database, maintains widely used Internet health portals (Terveysportti for health care professionals and Terveyskirjasto for the public), and publishes handbooks for health care professionals in Finnish.

Financing

Finland has two sources of public financing for health services (dual financing): municipal financing based on taxes and NHI based on compulsory insurance fees (Fig. 3.1). Municipalities fund municipal health care services (except outpatient drugs and transport costs). NHI funds private health care, occupational health care, outpatient drugs, transport costs and sickness allowance. Dual public financing creates some challenges for overall efficiency of service production.

Fig. 3.1 **Financial flow chart**



Notes: MSAH: Ministry of Social Affairs and Health; SII: Social Insurance Institution.

Municipalities

have the responsibility for organizing health services for their residents. For this, municipalities raise funding from municipal taxes, from state subsidies and from user-fees (Fig. 3.1). The main source of municipal funding for health care services is taxation. The majority of municipal health services are provided by municipal-owned health centres and hospital districts, but municipalities and hospital districts may also purchase services from the private sector. There is no true purchaser–provider split in the municipal health care system, as municipalities both fund services and own the service provision organizations, although there are exceptions to this.

NHI is divided into two parts: sickness insurance and income insurance. Sickness insurance covers outpatient drug reimbursement, reimbursement of medical costs for use by the private sector and rehabilitation services, and compensation of travel costs to health care units (including ambulance services). Income insurance covers sickness allowance, maternity leave allowance, rehabilitation allowance and reimbursement for employers for occupational health care services. Sickness insurance is funded by employees and the state. Income insurance is funded by employees and employers.

New Zealand

Ministry of Health's mission, vision and objectives

The Ministry of Health is a policy advisor to the Minister of Health, an agent of the Minister for monitoring and overseeing District Health Boards (DHBs), a funder of DHBs and national services (such as national screening services), and a provider of regulatory and other functions (e.g. public health).

The overall strategic objective of the Ministry of Health is "better, sooner, more convenient" services, thereby contributing to the Government's goal of all New Zealanders leading longer, healthier and more independent lives. The immediate-term strategic priorities feeding into this overarching objective are outlined in the Ministry's Statement of Intent:

1. Providing greater value for money.
2. Increasing clinical leadership.
3. Reducing waiting times for elective services, emergency departments and cancer treatment.
4. Devolving more services to primary and community settings.
5. Making the system more adaptable and resilient to deal with the challenges ahead.

Organization of health services and delivery systems

The New Zealand Public Health and Disability Act 2000 established DHBs. Governed by boards of directors that include locally elected members and ministerial appointees, the 20 DHBs are responsible for planning, funding and delivering most publicly funded health services to New Zealanders. DHBs' provider arms encompass hospital care, specialty care, community nursing and other functions.

DHBs are responsible for funding primary health care and contract with primary health organizations (PHOs) to provide primary health care services. DHBs and PHOs are responsible for implementing the Primary Health Care Strategy. Implementation of the Primary Health Care Strategy introduced significant changes for primary health care providers and consumers, and has been a significant investment for the Government. In the 2010/2011 financial year, total core PHO funding is estimated at NZ$ 764.8 million (US$ 642.1 million). The number of people enrolled with a PHO had remained steady, at just over 96% of the total estimated population (4 391 833), as at April 2011. PHOs have consolidated to reduce management costs, and there are currently 44. This phase of implementing the Primary Health Care Strategy is emphasizing 'Better, Sooner, More Convenient' (BSMC) primary health care. The BSMC priorities include:

- Better services through primary and secondary health professionals working more collaboratively.
- Patients accessing services sooner through providing more services in the community and creating smoother patient flow between different parts of the health system.
- More convenient access for patients through moving some services from hospital settings to primary health care settings.

Much health care is delivered by nongovernmental organizations (NGOs). These include providers with national contracts, such as the Royal New Zealand Plunket Society, which provides child health services, and providers that contract with their local DHB, such as community-based NGOs providing services to people with experience of mental illness. There are also approximately 275 Māori health

and disability providers that are Māori-owned and Māori-governed.

Health policy, planning and regulatory framework

The New Zealand Health Strategy and the New Zealand Disability Strategy sit alongside each other and together set the country's health and independence goals. Additional key strategies include He Korowai Oranga (the Māori Health Strategy), the aim of which is to support Māori families to achieve their maximum health and well-being, and the Primary Health Care Strategy, which aim to strengthen the comprehensiveness and integration of primary health care services throughout the country.

A wide range of health information is collected nationally and held in various collections maintained by the Analytical Services, National Health Board (Ministry of Health), and is used for a variety of analytical and research purposes at national, regional and local levels. Uses of the data include: monitoring contracts with providers, forecasting and setting of annual budgets, analysis of health needs, policy formation, assessment of policy effectiveness, performance monitoring and review, reporting and ad hoc queries, monitoring of health care strategies, and research into service provision.

Key national data collections include the following:

- The National Health Index, which is the cornerstone of health information. It was established to provide a mechanism for identifying every health care user by assigning each a unique number (known as the NHI number).
- The National Minimum Dataset, which uses a single, integrated collection of secondary and tertiary hospital health discharge data.
- The Cancer Registry, which is a population-based tumour register of all primary malignant diseases, active since 1948.
- The Mortality Register, which contains coded causes of death for New Zealanders who die in New Zealand and is based on the legal death certificate, or coroner's report, and autopsy reports. A complete data set of each year's mortality data is sent to WHO each year to be used in international comparisons of mortality statistics.
- The Mental Health Information National Collection, which contains information on specialist mental health and alcohol and drug services. The collection contains comprehensive information from DHBs and approximately 10% of NGOs.
- The National Booking Reporting System, which provides information, by health specialty and booking status, on how many patients are waiting for treatment, their assigned priority, their booking status and how long they have had to wait before receiving treatment
- The National Non-admitted Patient Collection (NNPAC), which provides national consistent data on non-admitted patient (outpatient and emergency department) activity.
- The Health Practitioner Index (HPI), the principal purpose of which is to uniquely identify health practitioners and to hold that information in a central, national database for use by the New Zealand health and disability sector.
- The Sector Services, which is a business unit within the Ministry of Health's Information Directorate which provides information and reports relating to health claims, provider payments and entitlements.

A full listing of national data collections and their content can be viewed on the following website at http://www.moh.govt.nz/moh.nsf/indexmh/dataandstatistics-collections.

Health care financing

Public sector funding is the major source of financing for health and disability support services. Approximately 80% of total health expenditure is paid for by government funds. Of total health expenditure, 68% is from Vote Health, which pays for core health services, such as hospitals, primary care, public health care, mental health care, addiction services, and care for older people. Most of the remaining public funds (10%) are from the ACC (Accident Compensation Corporation/ Social Security), which pays for accident and injury prevention and treatment. Private insurance pays for less than 5% of total health expenditure, while out-of-pocket spending accounts for between 14% and 17%. The balance is made up by non-profit institutions serving households (NPISH). These levels have remained roughly the same for the past 20 years.

Total Vote Health expenditure amounted to NZ$ 14 570 million (US$ 10 955 million) in 2009/2010, while DHB appropriations totalled NZ$ 11 589 million (US$ 8714 million). Most DHB funding is allocated using a population-based funding formula that gives each DHB the same opportunity, in terms of resources, to respond to its population's needs.

New Zealand has historically had a system of cost-sharing for doctors' visits and prescription drugs. The Commonwealth Fund 2007 International Health Policy Survey showed 12% of New Zealanders faced no out-of- pocket medical costs in 2007, while 10% faced more than US$ 1000 in out-of-pocket payments.

Singapore

Ministry of Health's mission, vision and objectives

The vision of the Ministry of Health is to develop the world's most cost-effective health care system to keep Singaporeans in good health. Its mission is to promote good health and reduce illness, ensure access to good and affordable health care, and pursue medical excellence. This is to be achieved through three strategies:

- Promote good health and reduce illness
- Ensure access to good and affordable health care
- Pursue medical excellence

Organization of health services and delivery systems

Ensuring the good health of the population is achieved through three cooperating ministries, as well as the private sector. The Ministry of Health is responsible for formulating national health policies for the provision of preventive, curative and rehabilitative health services. The Ministry also coordinates the development and planning of the private and public health sectors, and regulates health standards.

The Ministry of Environment and Water Resources is responsible for weather forecasting services; environmental and public health services, such as the management of water resources and the supply of drinking water to the nation, collection and treatment of used water, pollution and toxic chemicals and poisons; control of vectors that could spread diseases; and the hygienic preparation of food. The Ministry also licenses food-stall proprietors and looks after all public markets and food centres, public toilets and public cemeteries and crematoria.

The Ministry of Manpower is responsible for the health, safety and welfare of employed persons. The Ministry enforces requirements on employment conditions under the Employment Act, has provisions in the Workplace Safety and Health Act to safeguard the health and safety of the workforce, and administers the Work Injury Compensation Act to ensure fair compensation for persons with work-related injuries and diseases.

There is a dual system of health care delivery. The public system is managed by the Government, while the private system is provided by private hospitals and private general practitioners. The health care delivery system comprises primary health care provision at outpatient polyclinics and private medical practitioners' clinics, and secondary and tertiary specialist care in public and private hospitals. In addition, the 'people' sector, made up of voluntary welfare organizations and charities, further supplements the public and private health care systems through the delivery of intermediate and long-term care services, particularly for the elderly and chronically sick. Eighty per cent of primary health care services are provided by private practitioners, while government polyclinics provide the remainder. For hospital care, the ratios are reversed, with 80% provided by the public sector and the remainder by the private sector.

Patients are free to choose their health care providers within the dual health care delivery system, and can call to book an appointment or walk in for a consultation at any private clinic or any government polyclinic. For emergency services, patients can access the 24-hour accident and emergency departments located in government hospitals. The Singapore Civil Defence Force runs an emergency ambulance service to transport accident and trauma cases and medical emergencies to the acute general hospitals.

Primary health care involves the provision of primary medical treatment, preventive health care and health education. Primary health care is provided through an island network of 18 government outpatient polyclinics and over 2400 private medical practitioners' clinics. Each polyclinic is an affordable, subsidized, one-stop health centre, providing outpatient medical care, follow-up of patients discharged from hospital, immunization, health screening and education, investigative facilities and pharmacy services. At polyclinics, the average outpatient consultation fee is about $8 (US$6.50). In addition, Singapore citizens aged 65 and above, children up to 18 years of age and all schoolchildren are given a concession of up to 75% on their consultation and treatment fees. Other Singapore citizens are given a 50% concession. The private medical clinics are located in close proximity to population centres in the city, housing estates and satellite towns. The average outpatient consultation fee is within the means of Singaporeans. The needy elderly receive further help through the Primary Care Partnership Scheme (PCPS), which allows patients to go for consultations at private clinics, but pay polyclinic rates. PCPS is most helpful to those who cannot travel to polyclinics.

There are about 11 431 hospital beds in the 29 public and private hospitals and speciality centres; 77.2% of the beds are in the 14 public-sector, specialty centres and hospitals. The 16 private-sector hospitals are smaller, with a capacity of between 24 and 413 beds. The Government's role as the dominant provider of secondary and tertiary care allows it to manage the supply of hospital beds, the adoption of high-tech/ high-cost medicine, and cost increases in the public sector, which serves as a price benchmark for the private sector.

The eight public hospitals comprise six general hospitals, a women's and children's hospital and a psychiatric hospital. The general hospitals provide inpatient and specialist outpatient services, and a 24-hour emergency department. Seventy-five per cent of public hospital beds are heavily subsidized. There are also six national specialty centres for oncology, cardiology, ophthalmology, dermatology, neuroscience and dentistry. Tertiary specialist care in the areas of cardiology, renal medicine, haematology, neurology, oncology, radiotherapy, plastic and reconstructive surgery, paediatric surgery, neurosurgery, cardiothoracic surgery and transplant surgery is centralized in two of the larger general hospitals, the Singapore General Hospital and the National University Hospital. The private hospitals have similar specialist disciplines and comparable facilities.

The Government has structured all its 14 hospitals and specialty institutes as private companies, wholly owned by the Government and managed as not-for-profit organizations. This has granted the public hospitals management autonomy and flexibility to respond more promptly to the needs of their patients. In the process, greater financial discipline and accountability have been introduced. The corporatized health care institutions are also clustered into Regional Health Systems to deliver comprehensive and affordable quality health care services through cooperation and collaboration between public, private and voluntary non-profit health care establishments. The restructured public hospitals receive an annual government subsidy for the provision of subsidized patient care, and are subject to broad government policy guidance through the Ministry of Health. The Government has also introduced lower-cost community hospitals to provide intermediate subacute and rehabilitative care for patients who do not require the more expensive care provided by the acute general hospitals.

Support services for the hospital and primary health care programmes include forensic pathology, pharmaceutical services and the blood transfusion service. Except for forensic pathology and the blood transfusion service, which are centralized in the Health Sciences Authority, a statutory board under the Ministry of Health, most of the other services can be found in both the public and private sectors.

Dental care begins with preventive dentistry promoted through the Health Promotion Board. The Board targets students through a network of about 200 static clinics located in schools, as well as 30 mobile dental clinics. This, plus fluoridation of potable water and availability of fluoridated toothpaste, has greatly diminished dental decay and tooth loss. Public dental services are available in some polyclinics and hospitals, and in the National Dental Centre.

Health policy, planning and regulatory framework

The Singapore health care philosophy emphasizes the building of a healthy population through preventive health care programmes and the promotion of healthy living. Grassroot leaders, the Heath Promotion Board and relevant stakeholders across all sectors are actively engaged in the joint planning of initiatives to address the health needs of the local community. Singaporeans are encouraged, through the public health education programme, to adopt healthy lifestyles and be responsible for their own health, and are made aware of the adverse consequences of harmful habits like smoking, alcohol consumption, bad diet and sedentary lifestyles. The child immunization programme, which targets infectious diseases like tuberculosis, poliomyelitis, diphtheria, whooping cough, tetanus, measles, mumps, rubella and hepatitis B, is offered at government polyclinics, as well as private primary health care clinics. Evidence-based health screening programmes have been introduced for the early detection of common ailments, such as cancer, heart disease, hypertension and diabetes mellitus, as well as follow- up. These are available in both primary and secondary care settings. There is also a Workplace Health Promotion programme, advocating the adoption of healthy practices at workplaces to improve the productivity and efficiency of employees and also to enhance the work environment and culture.

The Government ensures that good and affordable basic medical services are made available to all Singaporeans through heavily subsidized medical services at public hospitals and government clinics. The basic medical package includes evidence-based medical practices, and is delivered cost-effectively by trained personnel. Experimental, non-evidence-based treatments, as well as cosmetic and aesthetic treatments, may be excluded.

The health care regulatory framework consists mainly of two parties; the regulator (comprising the Ministry of Health along with its statutory boards) and the regulated (comprising public and private providers). All hospitals, clinics, clinical laboratories and nursing homes are required to maintain a good standard of medical services through licensing by the Ministry. Health care professionals are self-regulated by their relevant professional bodies:

- Singapore Medical Council,
- Singapore Dental Council,
- Singapore Nursing Board,
- Singapore Pharmacy Council,
- Traditional Chinese Medicine Practitioners Board,
- Optometrists and Opticians Board,
- Allied Health Professions Council.

In addition, health-related products, such as medicines and medical devices, are regulated by the Health Sciences Authority.

Health care financing

In the 2009, Singapore spent about S$10.3 billion (US$7.1 billion) or 3.9% of GDP on health care. Out of this, the Government expended S$4.3 billion (US$2.9 billion).

The philosophy of Singapore's public health care delivery system is one of strong government support combined with individual responsibility and community support. Multiple tiers of protection have been built into the health care financing system to ensure universal coverage for all citizens. The first level of protection is through heavy government subsidies of up to 80% for patients who choose to stay in subsidized wards within the public hospitals. The second level of protection is provided by Medisave, a compulsory individual medical savings account scheme that helps Singaporeans to save and pay for their share of medical treatment without financial difficulty. The third level of protection is provided by MediShield and ElderShield, which riskpool the financial risk of patients suffering a major illness or severe disability. Finally, Medifund, a medical endowment fund, acts as the ultimate safety net for needy patients.

Individuals are encouraged to take responsibility for their own health by saving for their medical expenses. Medisave, as a national savings scheme, helps individuals set aside part of their income into Medisave accounts to meet their personal or immediate family's hospitalization expenses. Medisave can be used to pay for an individual's co-payment portion of his or her medical bill, as well as the premiums of approved medical insurance products. From 1 July 2011, Medisave can also help pay for mammograms and colonoscopies for screening.

In 2006, the Ministry of Health initiated the Medisave for Chronic Disease Management programme, a coordinated, nationwide effort to transform care for common chronic illnesses, starting with diabetes mellitus. Participating medical institutions include all public hospitals and polyclinics, as well as about half of the 1400 private primary care clinics in the country. Since then, the programme has been extended progressively to cover hypertension, lipid disorder, stroke, asthma and chronic obstructive pulmonary disease (COPD), schizophrenia and major depression. The programme seeks to improve chronic disease care through two chief avenues: (1) enhancing access, and (2) improving care. By liberalizing the use of Medisave to cover outpatient treatment for the chronic diseases (enhancing access) and implementing evidence-based disease management programmes, together with clinical quality improvement efforts (improving care), complications arising from these chronic diseases can be better prevented. Correspondingly, patients will be healthier and the risks of expensive hospitalization and potential disabilities will be reduced. The programme is supported by the participation of medical and allied health professionals in the public and private sectors, enhancements to IT systems to improve sharing of essential medical data, and education tools to improve patients' ability to manage their conditions.

MediShield is a low-cost, catastrophic illness insurance scheme designed to help members meet the medical expenses from major or prolonged illnesses, for which their Medisave balance would be insufficient. Individual responsibility is promoted through the features of deductibles and co-payment in MediShield. Annual premiums for MediShield can be paid from the individual's Medisave account. There are also private supplementary insurance products offering additional coverage. These are integrated with MediShield to provide a national risk pool for basic coverage.

Medifund is an endowment fund set up by the Government as a safety net to help poor Singaporeans pay for their medical care. Medifund is meant to be an avenue of last resort for patients who, despite heavy government subsidies and Medisave and MediShield coverage, are unable to pay for their medical expenses. Therefore, no Singaporeans are denied access into the health care system or turned away by the public hospitals because of their inability to pay. In 2007, part of Medifund was specifically set aside for needy, elderly patients (65 years and above).

ElderShield is an affordable, severe-disability insurance scheme designed to provide Singaporeans with basic financial protection against long-term care expenses. Introduced in September 2002, it was further reformed in 2007 to improve its benefits, and private insurers are now allowed to provide supplementary products with higher coverage.

Public-sector health services are provided to cater for lower income groups who cannot afford private-sector charges, and also to set the benchmark for the private sector on professional standards and charges. To support the latter objective, the Government requires public hospitals to publish basic consultation and ward charges to ensure greater price transparency. The Ministry of Health also publishes hospital pricing data and bill sizes for common conditions on its website.

Switzerland
Overview of the health system

The political system in Switzerland is characterized by both liberalism and federalism. This is also reflected in how the health care system is organized.

- The liberal orientation of the state is reflected in the constitutions of the Swiss Confederation and the cantons. The state basically only intervenes when private initiative fails to produce satisfactory results, i.e. it acts only as a safety net or provider of last resort. This explains the relatively major role that actors outside the public sector play in Switzerland's health care system.
- The principle of federalism is anchored in the federal constitution. The Swiss Confederation can legislate only when expressly empowered to do so by the constitution. The constitution only grants limited powers to the Confederation over the health care system. In addition, the cantons may delegate tasks to the municipalities.

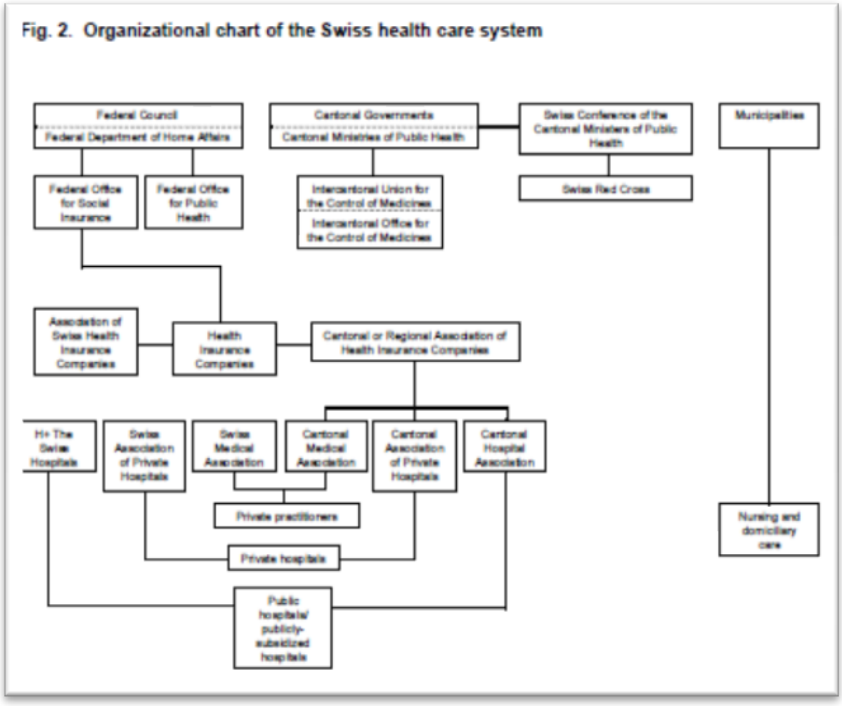
These principles result in a complicated system in which many different actors are involved.

The most fundamental changes in recent decades have come about following the enactment of the health insurance law that entered into force on 1 January 1996. This law is still being implemented and is being continually adjusted by further ordinances and revisions passed by Parliament (see the section on *Health care reforms*).

Organizational structure of the health care system

This section describes the responsibilities of the public authorities and the most important private actors. The main functions and interrelationships of these actors are outlined briefly below and shown in Fig. 2.

Fig. 2. Organizational chart of the Swiss health care system



The federal government

The federal constitution lists in full the legally defined responsibilities of the federal government. Those areas that relate principally to health are:

Eradication of communicable or very widespread or virulent diseases of humans and animals

- This constitutional duty is further elaborated through several acts of legislation known as federal laws, ordinances and decrees;
- epidemics law: Federal law on combating communicable diseases in humans (18 December 1970);
- immunobiological products ordinance: Ordinance on immunobiological products (23 August 1989);
- blood, blood products and transplant material decree: Federal decree on the control of blood, blood products and transplant material (22 March 1996);
- foodstuffs law: Federal law on food and consumer safety (9 October 1992);
- narcotic substances law: Federal law on narcotic substances and psycho- tropic substances (3 October 1951);
- poisons law: Federal law on trade in poisons (21 March 1969);
- the federal government's activities aimed at preventing AIDS and addiction (embodied in several ordinances).

The Swiss Federal Office for Public Health is the section of the Federal Department of Home Affairs with the greatest responsibility for these areas. Its work is supported by a large number of special commissions.[5] The task of implementing these laws has largely been delegated to the cantons.

Promotion of exercise and sport

The Federal law on exercise and sport (17 March 1972) empowered the federal government to issue further legislation in support of the following areas of activity:

- physical exercise and sport in schools
- gymnastics and sports clubs as well as sports events
- research on sports science
- the building of national sports facilities
- a gymnastic and sports school.

Besides these responsibilities the federal state runs the Organization for Youth and Sport, which aims to encourage young people (aged 10–20 years old) to undertake further sports training and to lead healthier lifestyles.

Social insurance provision

The constitutionally defined duty of the federal government with regard to the provision of social insurance cover is further elaborated through other acts of legislation, including:

- the health insurance law: Federal law on health insurance (18 March 1994)
- the accident insurance law: Federal law on accident insurance (20 March 1981)
- the disability insurance law: Federal law on disability insurance (29 June 1959)
- the military insurance law: Federal law on military insurance (19 June 1992).

The Federal Office for Social Insurance is responsible for all these social insurance policies mentioned above. The only exception to this is military insurance, which is the responsibility of the Federal Office for Military Insurance. Military insurance covers damage to health sustained during military service or peacetime duties for the federal government, such as civil defence duties, emergency relief and peacekeeping duties.

The federal government is the sole provider of disability insurance and military insurance. This contrasts with compulsory health insurance and compul- sory accident insurance, which are provided by a variety of insurance funds under the supervision of the Federal Office for Social Insurance.

In 1945 the federal government was given a constitutional mandate to establish a system of maternity insurance, to cover women for loss of pay during pregnancy and childbirth. All attempts to do so in the past have failed to pass in public referenda (1984, 1987 and 1999).

Medical examinations and qualifications

Since as long ago as 1877, when the Federal law on the freedom of medical personnel in the Swiss Confederation (19 December 1877) was enacted, the federal government has been responsible for the accreditation of "scientific professions". This term covers doctors, dentists, veterinarians and pharmacists. They are all required to pass a federal examination, and having done so are awarded a diploma that guarantees them freedom to practice anywhere in Switzerland, providing they also apply for a licence to practice from the can- tonal authorities (see below). Specialist medical training is regulated by the Swiss Medical Association (see below).

Genetic engineering, reproductive medicine, transplant medicine and medical research

There is a public consensus that the federal government should have the main responsibility for genetic engineering, reproductive medicine, transplant medicine and medical research. These activities, however, are the subject of intense controversy. Since 1992 the federal government has had a constitutional mandate to legislate on reproductive and genetic technology. The parliament passed a law on reproductive medicine in autumn 1998. A federal law on genetic investigations in humans has been drafted. The federal government has had a constitutional mandate to regulate transplant medicine since 7 February 1999. The Federal Expert Commission for Biological Safety advises the federal government and cantons on genetic engineering and biotechnology.

Statistics

The statistics law (Federal statistics law (9 October 1992)) requires the federal government to compile data on health and the health care system. The health insurance law contains additional regulations that empower the Federal Council to collect statistical data necessary to implement the law such as expenditure data, utilization data, etc.

Labour laws

The legislation on labour and the protection of workers (Federal law on labour in industry and trade (13 March 1964)) empowers the federal government to compel employers to take the necessary measures to protect the health and safety of the workforce.

International relations

As part of its remit to promote international cooperation, the Swiss Federal Office for Public Health collaborates with the World Health Organization (WHO) and the Council of Europe. Other federal bodies and the Swiss Conference of the Cantonal Ministers of Public Health are also active in this field.

The cantons

The health service is one of the areas of government activity in which the cantons have a declining but still relatively high degree of independence. The cantonal activities can be divided into the following four areas, which are de- scribed in more detail below:

- regulation of health matters
- provision of health care
- disease prevention and health education
- implementation of federal laws.

Regulation of health matters

Licensing of the health professions

The cantons determine the conditions under which individuals in health pro- fessions may receive a licence to practice.

Authorization to open a medical practice or pharmacy Market authorization and control

of medicines

The need for national standardization in registering and controlling medicines led to an intercantonal

agreement on this matter as long ago as 1900. The cantons established the Intercantonal Union for the Control of Medicines for this purpose.

Provision of health care

Inpatient care (hospitals and residential nursing homes)

Most cantons operate their own hospitals; some also subsidize private hospitals. There are also private clinics that do not receive any state support. The revised health insurance law requires the cantons to draw up plans for providing hospital care according to need and to produce a list of hospitals and nursing homes that are eligible for reimbursement under compulsory health insurance. This list includes public and publicly subsidized hospitals but may also include private providers.

Global budgets for public and publicly subsidised hospitals were introduced in five cantons in 1994 and have since been introduced in other cantons. The exact way in which these budgets operate varies between cantons. For more detail see the section on *Payment of hospitals*. Objections to cantonal decisions regarding hospital lists and global budgets can be lodged with the Federal Council.

Nursing and home care

The cantons can provide nursing and home care or delegate this responsibility. Most cantons delegate at least some of these tasks to the municipalities. The canton is responsible in any case for licensing providers of nursing and home care services.

Fees

The cantonal government endorses the fee schedules negotiated and agreed between service providers and associations of health insurance funds in each canton. If the parties are unable to agree, the cantonal government determines the fee schedule. Objections to decisions made by cantonal governments on fees can be lodged with the Federal Council (see the section on *Planning, regulation and management*).

Emergency, rescue and disaster-aid services

Emergency, rescue and disaster-aid services include emergency transport and ambulance services.

Basic and specialty medical training

Basic and specialty medical training is provided at seven cantonal universities and public hospitals and clinics. Training follows the federal regulations on medical examinations and qualifications (see above). The Swiss Medical Association (Foedaratio Medicorum Helveticorum) regulates postgraduate train- ing for doctors.

Training in paramedical occupations

The cantons regulate all major health-related occupations. Training is delegated to the Swiss Red Cross (see the section on *Human resources and training*).

Disease prevention and health education

The cantons' activities in disease prevention, health promotion and health education vary widely both in scope and nature. Numerous diverse projects and activities aim primarily to prevent disease. Nevertheless, there are no strategic cantonal objectives covering the whole of Switzerland and no means for implementing such national projects. In 1989 the federal government and the

Association of Swiss Health Insurance Companies set up the Swiss Foundation for Health Promotion, partly with the aim of remedying this situation. In mid-1996 the Foundation was designated as the national institution responsible for initiating, coordinating and evaluating measures designed to promote health and prevent disease in accordance with Article 19 (§ 19) of the health insurance law 1994 (see the section on *Public health services*). The Foundation is supervised by the Federal Office for Social Insurance, but the management body of the Foundation includes representation from the cantons.

Implementation of federal laws

In most of its areas of responsibility, the federal government has delegated powers of implementation to the cantons.

The municipalities

The cantonal health laws confer responsibility for health policy on the municipalities. The responsibility for providing nursing care for certain vulnerable groups is usually delegated to the municipalities, with the emphasis on home care, residential and nursing homes for elderly people and community-based mental health services.

The municipalities have delegated responsibility to independent organizations for most home care services. Larger municipalities and associations of municipalities often run their own residential and nursing homes for elderly people. Municipalities run nursing homes and hospitals either alone or in con- junction with other municipalities (through hospital associations) or are represented on the boards of such facilities. The municipalities are also responsible for supporting and counselling pregnant women and mothers, providing obstetric services and health and dental care in schools.

Health insurance companies

In 1999, there were 109 insurance companies that offered compulsory health insurance policies in Switzerland (this compares to 207 companies offering statutory health insurance in 1993). Only those insurance providers who comply with the requirements of the health insurance law and are registered with the Federal Office for Social Insurance may provide compulsory health insurance (CHI). The main requirement being that no profit should be made from compulsory health insurance activities.

There are many insurance companies active in providing insurance policies of different types, including occupational and non-occupational accident insurance, old age and disability insurance, and maternity insurance.

The registered health insurance companies that offer compulsory health insurance also dominate the market for supplementary health insurance policies whereas the non-registered insurance companies provide other types of insurance and have a small share in the market for supplementary health insurance policies. In 1998 there were 63 registered insurance companies offering supplementary health insurance policies, compared with 61 non- registered companies.

The registered insurance companies that are allowed to offer compulsory health insurance have developed historically and may be regional, federal, religious or occupational based. They are not allowed for any reason to refuse an individual's application for compulsory health insurance coverage. Since the revised health insurance law was enacted in 1996, compulsory health insurance policies are uniform, i.e. covering the same package of benefits.

Table 1 shows the size and market share of different insurance companies in Switzerland. Seventy-one per cent of all insurance companies cover less than 10 000 people; these insure only 3.2% of the total insured population. The insurance companies covering less than 10 000 people insure 2500 people each on average. The insurance companies that cover between 100 001 and 1 million people cover 68.4% of all insured people. The largest company covers over 1 million people, which represents 16.8% of the total insured population.

The regulation of the insurance companies in relation to administration, accounting and premium calculations intensified substantially in 1996 when the revised health insurance law came into force; many small insurance companies could no longer participate in this drive for professionalism and withdrew or merged with larger insurance companies. This has not yet resulted in any action on monopolies by the Swiss Competition Commission as 109 companies are still active in the CHI market in 1999 (see Table 2).

Table 1. Number and size of compulsory health insurance (CHI) providers, 1997

Insured persons per CHI provider	Number of CHI	Number of insured	Percentage of
<1 000	32	16 677	0.2
1 001–10 000	60	213 142	3.0
10 001–100 000	23	832 613	11.6
100 001–1 000 000	14	4 909 494	68.4
>1 000 000	1	1 210 566	16.8
Total	**130**	**7 182 492**	**100**

Source: Association of Swiss Health Insurance Companies (*1*)

Table 2. Trend in total number of compulsory health insurance (CHI) providers, 1993–1998

Year	Number of CHI providers	Annual change
1993	207	–
1994	178	-29
1995	166	-12
1996	145	-21
1997	130	-15
1998	119	-11

1999	109	-10

Source: Association of Swiss Health Insurance Companies (*1*)

The health insurance companies have banded together to form cantonal and intercantonal associations that negotiate fees with service providers. Registered insurance companies can request the canton to set a global budget for financing hospitals and nursing homes as a one-off temporary measure to contain an excessive increase in expenditure. This provision has never been exercised.

All health insurance companies in Switzerland are members of the Association of Swiss Health Insurance Companies. The main functions of the Association are:

- public relations;
- representing the interests of the members to political bodies, including influencing the legislation process, influencing the work on reforming the fee schedule and representing the insurance companies in federal commissions;
- compiling statistics, including collecting extensive data on expenditure and utilization from its members which is primarily used for the fee negotiations;
- negotiating with service providers at the national level on fee schedules, quality assurance and other matters;
- supporting the cantonal associations when they appeal against the decision of a cantonal government to the Federal Council;
- training in areas of health insurance accounting, administration and management.

On 1 January 1996 when the revised health insurance law came into force, the registered insurance companies established a joint organization, known as Foundation 18. Its responsibilities are to meet the financial obligations of insurance companies in financial difficulty, to be responsible for risk adjustment between the registered insurance companies and to meet international obligations for reimbursing health care services.

Professional associations

The doctors are organized into cantonal medical associations. These negotiate fee levels with the cantonal associations of health insurance companies. Membership of the cantonal medical associations is not compulsory but everyone who is a member of the Swiss Medical Association has to be member of a cantonal association.

The Swiss Medical Association regulates and accredits postgraduate medical training for doctors. The Association only confers qualifications for postgraduate medical training on doctors who are members.

The Swiss Dental Association, like the Swiss Medical Association, is a professional and representative organization as well as a scientific society for dental medicine. The Swiss Dental Association collaborates with universities and specialist colleges to find ways to incorporate new concepts and methods of prevention and therapy into practice. As a representative organization, the Swiss Dental Association pursues a number of other functions, including legal advice, political representation and public relations and assistance in establishing and developing dental practices.

Pharmacists are members of the Swiss Pharmacists' Association. Its main functions are similar to the

other professional associations and include provision of scientific information for pharmacies.

Practitioners of health-related professions other than doctors are represented by organizations specific to their occupation. These organizations represent the interests of their members in dealing with employers and are involved in drawing up the training guidelines issued by the Swiss Red Cross and in the ongoing development of the training system. Various occupational organizations also offer courses of advanced and specialist training.

Most of the occupational organizations are represented by an umbrella organization, the Swiss Federation of Healthcare Professional Associations, which represents its members' interests at the national level. It has a seat on the federal government's advisory committee that considers proposals for extending the package of compulsory health insurance benefits.

Hospital associations

The Swiss Association of Hospitals is called "H+ The Swiss Hospitals". Its main tasks are to represent the interests of all hospitals, provide in-service training for managers, develop management tools (such as cost accounting) and compile comparative statistics. It collects both administrative statistics such as wage costs and input costs as well as medical statistics about length of stay and service intensity. The private hospitals are also members of the Swiss Association of Private Hospitals. The Association's main functions are public relations, legal advice, information provision and political representation.
At the cantonal level, the public and publicly subsidized hospitals have formed hospital associations that negotiate fees with the health insurance companies. Private hospitals are often also members of the cantonal hospital associations.

Voluntary and consumer organizations

A large number of organizations concentrate on specific diseases, such as the Swiss Cancer League, the Swiss League against Rheumatism, the Swiss Lung Association and support organizations for people with AIDS. They fulfil major functions, including prevention, public relations, counselling and liaison with patients.

Patient organizations work on various committees to represent the interests of the insured population. They have the right to be consulted in the process of negotiating fee schedules between insurance companies and service providers. In general, however, the recipients of services, including insured people, patients and relatives, tend to be in a weak position.

The responsibilities of the various actors described above have developed over time, and in some instances there is no clear or objective demarcation of responsibility. This leaves room for interpretation and, together with the coexistence of cantonal and federal regulations, produces a great need for consultation if inconsistencies and contradictions are to be avoided.

Planning, regulation and management

Switzerland's health care system is a liberal and decentralized system. Providers are free to choose where to locate and patients are free to choose providers within a canton.

Regulation of health care services

The basic benefits package and therefore the services covered by the compulsory health insurance are defined in law (see the section on *Health care benefits and rationing*). The insurance provider will reimburse service providers if the services are clinically effective, appropriate and cost-effective. These criteria also apply to pharmaceuticals and to medical devices and medical aids (see below). The service providers or their associations are also required to develop and implement methods of assuring and improving quality. The National Association for Promoting Quality in Health Care is the main body responsible for developments in quality management and is attempting to monitor, coordinate and support work in this area on a national basis. It is an independent network made up of representatives of many of the key actors in the health sector discussed in this section.

So far, the requirement that: services should be clinically effective, appropriate and cost effective to qualify for reimbursement has only been applied to considerations of services which are to added to the benefits package. Existing services have not been subjected to scrutiny under these criteria. The development of measures to promote quality assurance and improvements varies greatly between cantons and health care sectors. Outline agreements have been reached between insurance companies and service providers in the hospital sector, but work has only just started on implementing measures of this kind in ambulatory care.

Regulation of pharmaceuticals and technology

The Federal Department of Home Affairs decides which medicines are covered by compulsory health insurance and at what price they should be sold. It also determines which laboratory analyses and investigations or medical devices and medical aids are covered by the compulsory health insurance.
The Federal Department of Home Affairs consults five different commissions: four of which are specialist commissions, such as the Federal Commission for Pharmaceuticals, and the fifth is the Federal Commission for Fundamental Questions of Health Insurance, which has greater authority than the other four but is still only advisory. It has 17 members including representatives from each of the other four commissions, the Federal Office for Public Health, the Data Protection Agency, Intercantonal Office for the Control of Medicines, the Swiss Competition Commission and the cantons. It attempts to unify practice and ethical considerations related to defining the benefits package. The other commissions have to comply with the decisions of this Commission. (See the section on *Pharmaceuticals* for more detail on pharmaceutical policy and regulation.)

Health policy

Many of the attempts by the federal government, cantons and other actors to achieve a common health policy have failed. A new attempt is currently being made. Health policy is understood here in its broadest sense. It covers not only organizing the provision of health services but also health promotion and the prevention and control of diseases. Health policy defined in this way encompasses not only policy on health care but also all policy areas that affect the health of the population, including economic policy, environmental policy and social policy. This concept of health policy is substantially influenced by the WHO policy framework for health for all (see the subsection on *Health for all policy* in the section on *Proposed reforms*). A prominent element in the new health policy currently under discussion is the creation of a Swiss Health Observatory to eliminate the notorious information deficits that hamper the development of strategies on health policy.

United Kingdom

Overview of the health care system

The period since 1997 has witnessed a series of organizational changes to the health care system in England designed to shift responsibility away from the Department of Health at the centre to regional and local levels. Major reforms included the creation of PCTs, which are responsible for commissioning health services for geographically defined populations; the introduction of new types of NHS providers, FTs, with greater financial and managerial autonomy; and the greater use of private-sector capacity to deliver publicly funded health care. At the same time the Department of Health created a number of new semi-independent bodies to assist in setting priorities and monitoring standards for different parts of the health care system.

Health services in England are mainly financed by government through general taxation and NICs and are largely free at the point of use. Established in 1948, the NHS provides preventive medicine, primary care and hospital services to all those "ordinarily resident" in England. Around 13% of the population is covered by voluntary health insurance. In England, this is most commonly referred to as PMI, and henceforth this is the term used in this report. PMI mainly provides access to acute elective care in the private sector.

Responsibility for publicly funded health care rests with the Secretary of State for Health, who is accountable to the United Kingdom Parliament. The Department of Health is the central government body responsible for setting policy on the NHS, public health, adult social care and other related areas. The Treasury plays a key role through its influence in setting the national budget for publicly funded health care. Leadership in the Department of Health is provided by the Permanent Secretary, who is responsible to the Secretary of State and parliament for the way the department functions, and the Chief Executive of the NHS, who provides strategic leadership for the NHS and social care.

At a national level, the Department of Health is assisted in setting and monitoring standards and regulating the health system by a range of government and independent bodies, often called "arm's-length" bodies. The most significant of these are:

- The Care Quality Commission (CQC) was established in 2009 to take on the roles of the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. It promotes quality improvement in the NHS and the independent sector 3 and is responsible for assessing the performance of NHS and independent-sector organizations.
- Monitor (the Independent Regulator of NHS Foundation Trusts) regulates FTs.
- Health Protection Agency (HPA) is responsible for protecting public health.
- National Institute for Health and Clinical Excellence (NICE) was established in 1999, primarily with responsibility for assessing and issuing guidance on new and existing medicines, treatments and procedures in the NHS. Since then, its role has been extended to include guidance on public health.

The Department of Health operates at a regional level through 10 SHAs, which are responsible for ensuring the quality and performance of local health services within their geographic area. In addition, the Department of Health and SHAs collaborate with regional government offices, which are central government bodies responsible for regional programmes working across the areas of responsibility of all central government departments. Responsibility for commissioning health services at the local level lies with 151 primary care organizations, mainly PCTs,4 each covering a geographically defined population of, on average, just over 340 000 people. PCTs are monitored by SHAs and are accountable to the Secretary of State for Health. The Department of Health allocates 80% of the NHS budget to PCTs using a weighted capitation formula that takes account of population size, age distribution and various indicators of health care need as well as unavoidable differences in costs between different geographic areas. Most publicly funded health services are commissioned by PCTs. Since 2005, GPs have played a role in commissioning through the development of practice-based commissioning (PBC).

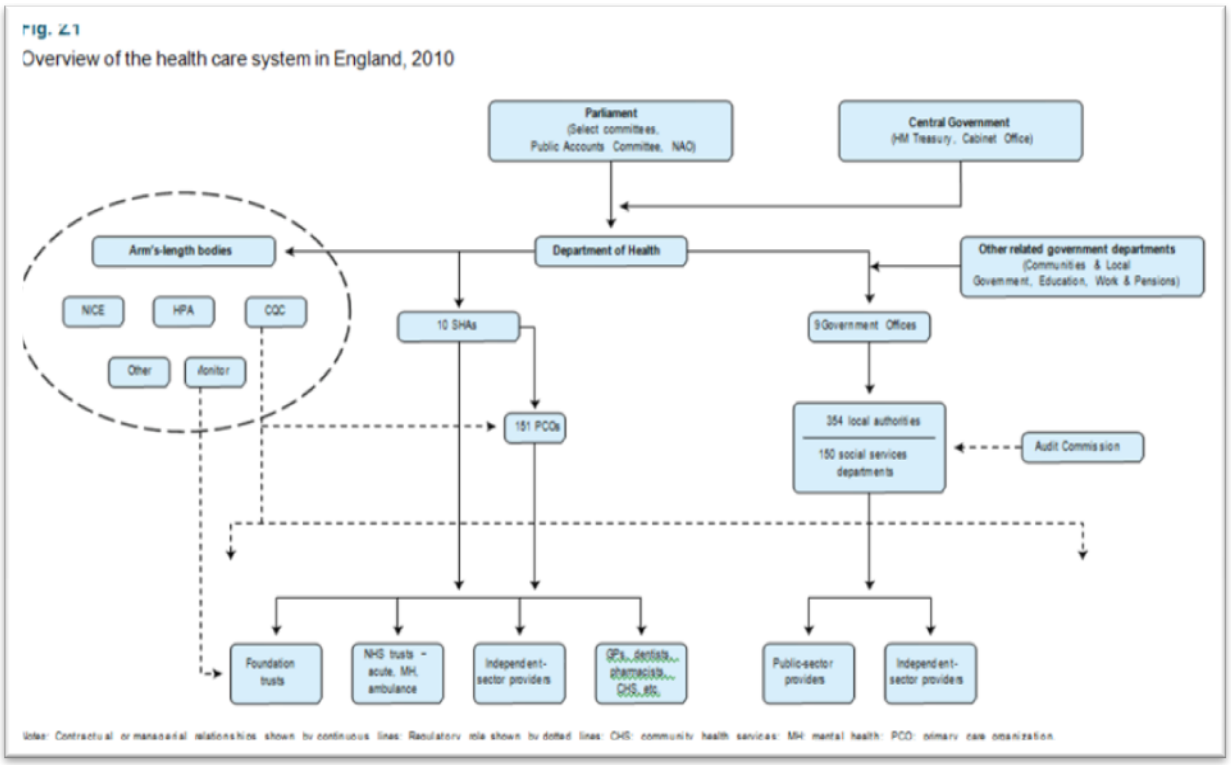
NHS-funded primary care is provided in a range of different ways. The first point of contact for general medical needs is usually self-employed GPs and their practices, who are typically engaged through a general medical services contract or a personal medical services contract (these are discussed in more detail in Chapter 3), although GPs may also be employed directly by alternative providers (e.g. the voluntary sector, commercial providers, NHS trusts, PCTs). In addition, community health services (e.g. district nursing, physiotherapy), NHS Direct (a telephone and Internet service), NHS walk-in centres, dentists, opticians and pharmacists are also part of NHS primary care services.

NHS-funded secondary care is provided by salaried specialist doctors (known as consultants), nurses and other health care professionals (e.g. physiotherapists and radiologists) who work in government-owned hospitals known as "trusts". A small private sector exists alongside the NHS, funded through private insurance, direct payments from patients or publicly funded payments by PCTs and the Department of Health; this mainly provides acute elective care. The CQC regulates the independent health care sector through registration, annual inspection, monitoring complaints and enforcement, within the legal framework set out in the Care Standards Act 2000 and subsequent amendments and statutory instruments.

Other key organizations in the health care system include the BMA and professional groups such as the Royal Colleges (representing different medical and nursing specialties), the British Dental Association (BDA), trade unions representing NHS staff such as UNISON, Unite the Union, the GMB (Britain's General

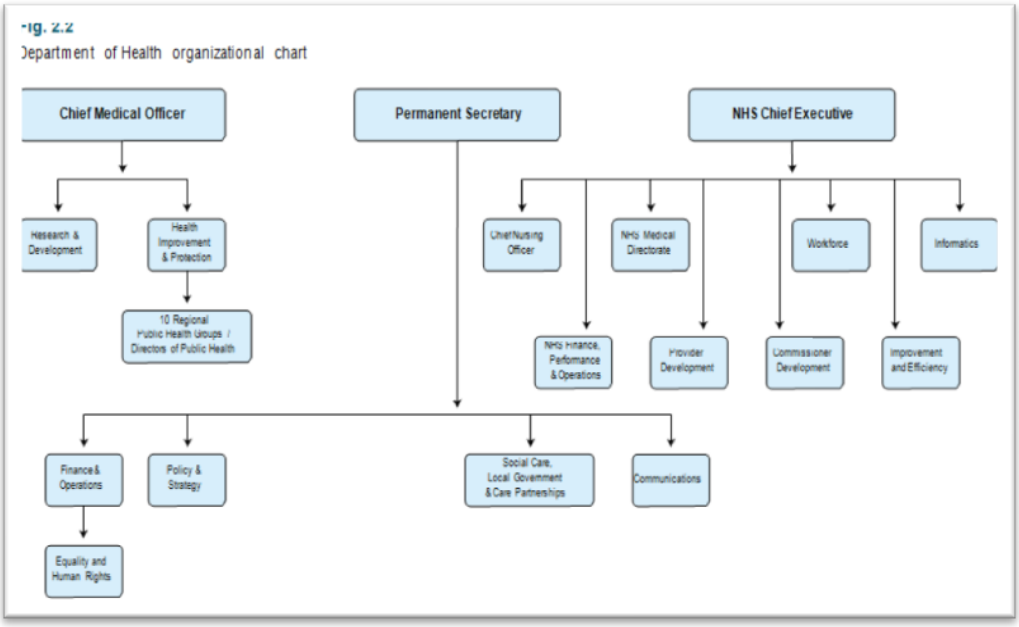
Union), and the Hospital Consultants and Specialists Association, and the NHS Confederation (representing NHS organizations and responsible for negotiating pay agreements with the professional bodies).

Fig. 2.1 shows the organizational structure of the health care system in England in 2010.



Organizational overview

From the outset of the NHS in 1948, the organization of health services in England has undergone a process of continual change and adaptation. The election of a Labour Government in 1997 heralded a series of strategic and organizational changes that were formulated in government white papers outlining structural, managerial and funding changes to the NHS over a period of 13 years. A new Conservative and Liberal Democrat Coalition Government was elected in May 2010 and this appears to signal yet more changes to the structure of the NHS. The current roles and responsibilities of the key participants in the health system:



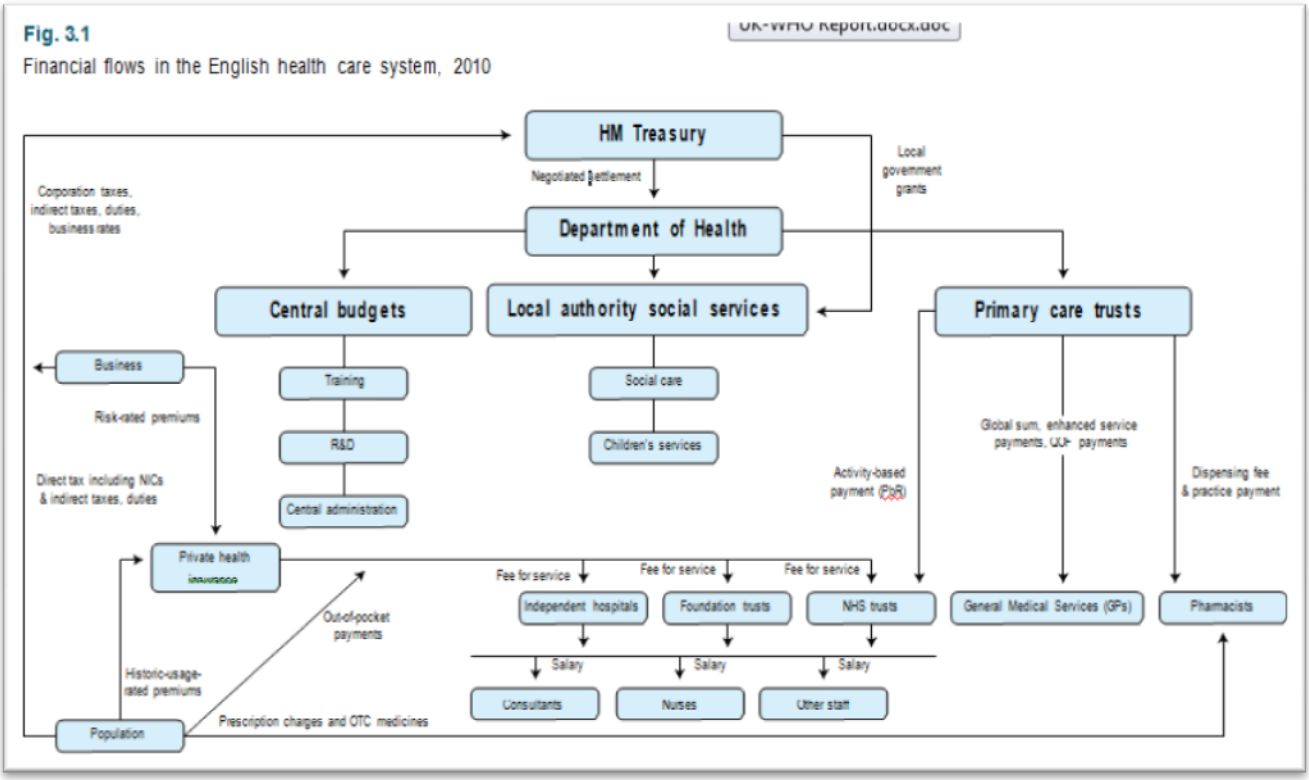
Financing

Health services in England are mainly financed from public sources, primarily general taxation and NICs. However, some care is funded privately: through PMI, by user charges for NHS services although most are provided free, by direct payments by individuals for items such as OTC drugs and medical appliances, or by direct payments by individuals for health care delivered by NHS, private-sector or voluntary-sector providers (Fig. 3.1).

Public sources of finance for health care are allocated by central government (HM Treasury has responsibility for this) to the Department of Health, which is then responsible for the further disbursement of monies. Since 1998, the size of the Department of Health's budget for the following three years has been fixed every two years following a process of negotiation with the Treasury known as the Spending Review.

Fig. 3.1

Financial flows in the English health care system, 2010



The NHS publicly funded system consists of organizations that deliver services (service providers) and organizations that contract for (commission) services (mainly PCTs). Each year, the Department of Health allocates around 80% of the total NHS budget to PCTs using a weighted capitation formula. PCTs are responsible for purchasing primary, community, intermediate and hospital-based services from a range of providers, mainly in the public sector but including private- and voluntary-sector providers. Since 1999, there have been significant changes to the way in which PCTs pay for health services, particularly in the hospital sector, with the introduction in 2003–2004 of activity-based funding – developed in England as PbR. Important changes have also been made to the system of paying GPs and specialist doctors (consultants).

Regulation

In the health care sector, much of what is observed is independent regulation through a range of bodies (Table 4.1). NHS hospitals are in the process of attaining greater autonomy from the Department of Health, although they remain subject to a system of external audit and inspection that has been developed

Table 4.1

Decentralization of functions and regulatory institutions in England

Function	Type of decentralization	Regulatory institution
Set standards	Centralization	Department of Health
	Delegation	NICE
Monitoring	Delegation	CQC, Audit Commission, NAO, NPSA, Monitor
	Deconcentration	SHAs
	Devolution	Local government overview and scrutiny committees
Enforce regulation	Privatization	GMC, General Dental Council (GDC), Nursing and Midwifery Council, General Pharmaceutical Council, General Optical Council, General Chiropractic Council, General Osteopathic Council, Health Professions Council
	Delegation	CQC, General Social Care Council, Monitor
	Deconcentration	NHS trusts

and extended since 1999. PCTs still operate within a target- based framework, reflecting their responsibility for the use of public funds to meet the health needs of their local populations. Health care professionals had retained a significant degree of autonomy in regulating their practice, although there have been significant changes in recent years.

United States (US)

Healthcare Structural Characteristics

The reimbursement system in the US is based on a mixed public/private third-party payment system whereby government, employers, and individuals share the cost of care. Premiums are paid to private insurance companies for private coverage either by individuals or employers. Government coverage provided at federal (Medicare, DoD, BIA) and state levels (Medicaid) to statutorily defined populations (elderly, poor, disabled, veterans, etc.). Many private insurers also cover Medicare and Medicaid populations financed by the government.

Population size by payer

- 200 million Americans have some form of private health coverage
- Increasing trend towards large companies self-insuring
- 70-80 million Americans have public coverage
- 44.0 million (14% of the population) Medicare beneficiaries
    - ~90% of these have out-patient prescription drugs coverage
    - 36.7 million are age 65+
    - 7.3 million are disabled
    - Certain special populations covered like end stage renal disease
- Roughly 15% of us population or ~45 million people are uninsured

Payers, whether government or private, manage costs through a system of coverage policies, resource utilization controls, and contracting. Payers (including employers) are increasingly demanding evidence-based approaches to coverage and payment for new technologies. Healthcare payment and delivery in the US is dominated by government (Medicare, Medicaid) and private payers (or managed care organizations). Payers rely heavily on decentralized health technology assessments when making coverage determinations. Currently value is determined through analysis of clinical and economic outcomes evidence. It is neither a uniform, nor standardized process by any means. Although there are general HTA criteria that payers adhere to, variances do exist as each payer defines their respective technology coverage processes and criteria.

Comparative effectiveness research (CER) has been identified as a key component of ongoing healthcare reform efforts, in part to develop a standard set of guidelines and criteria for evaluating novel technologies; comparing outcomes of novel technologies (and their associated coverage and payment) to established , standards of care and other relevant comparators.

Diagnostic pricing is frequently benchmarked by commercial payers to the Medicare Clinical Lab Fee Schedule, though non-standard approaches (e.g.., direct payment negotiation with payers) is possible in some cases Health technology assessment criteria and diagnostic pricing standards may change as health care reform policy evolves.

Medicare

Medicare is the largest single payer in the United States and plays a significant role in setting reimbursement. Medicare is a federal health insurance program enacted in 1965 to provide healthcare coverage for those aged 65 and older regardless of income or medical history. The program was expanded in 1972 to include those under the age of 65 with permanent disabilities or end-stage renal disease (ESRD). It was expanded again in 2001 to include those under the age of 65 with amyotrophic lateral sclerosis (ALS). As of November 2008 over 45 million Americans covered through Medicare's various programs with 38 million over the age of 65 and 7 million under the age of 65 with disabilities.

Medicare coverage is split into 4 parts: A, B, C, and D (11)

- Part A Coverage
  - Covers inpatient hospital services, skilled nursing facility, home health, and hospice care
  - Accounted for approximately 40% of Medicare benefit spending in 2008
  - Individuals are entitled to Part A if they or their spouse are eligible for Social Security payments and have made the appropriate payroll tax contributions for 10 or more years
- Part B Coverage
  - Helps pay for physician, outpatient, home health, and preventive services, including outpatient clinical laboratory services. Accounted for 27% of benefit spending in 2008
  - Individuals are entitled to Part A services may enroll in Part B benefits, but this coverage is considered voluntary (95% of Part A participants also enroll in Part B benefits)
- Part C Coverage
  - Advantage Plans (like HMOs and PPOs) are sometimes referred to as Medicare Part C
  - These are private commercial plans that have been approved by Medicare and provide all of beneficiaries' Part A and Part B benefits
  - Often times, they will also include Part D drug coverage
  - Medicare Advantage Plans normally have lower co-pay than for patients with Medicare alone
- Part D Coverage
  - Medicare Part D is prescription drug coverage
  - Beneficiaries must be enrolled in Medicare before they can apply for coverage by Part D but every enrollee is eligible
  - In most cases, beneficiaries will pay a monthly premium for the level of Part D coverage they select and benefits are provided by private companies

Reimbursement Methods

As one of the fastest growing portions of healthcare costs in the United States, drug expenditures have been a matter of concern in the U.S. for many years. The United States has a health care system involving a combination of private and public payers adopting a variety of pharmaceutical

reimbursement policies. The private insurance companies may negotiate drug prices, rebates, and drug-volume discounts with pharmaceutical manufacturers. The three largest U.S. government purchasers of pharmaceuticals – Medicare, Medicaid, and the Department of Veterans Affairs (VA) – use a mixture of methods, including reimbursement-rate setting, price ceilings, negotiated prices, discounts, and rebates, as well as other cost and utilization-management tools.

Reimbursement Rate Setting. This technique can apply when a payer acts as a price setter and dictates the amount it will pay. To be successful, reimbursement rate setting requires the payer to have significant buyer leverage. Reimbursement rate setting is not used solely by the U.S. government; some western European countries also use the payment method. An example of this approach involves drugs covered in part B of the U.S. Medicare program. The Medicare program in the U.S. is a publicly funded, federal government administered program for persons aged 65 and over and certain disabled persons. Part B of the program covers the cost of a limited number of prescription drugs and some forms of care. In addition, in the U.S., some physicians, such as cancer specialists, may purchase select drugs from a wholesaler or other distributor, administer the drug to a patient and subsequently be reimbursed for the drug by the payer – at a rate that may or may not be the same as the purchase price. Part B of the U.S. Medicare program sets the rate at which it will reimburse providers for such drugs that are furnished incident to a physician's service.

Price Ceilings. This is the maximum reimbursement rate a health system will pay. Price ceilings are used by the U.S. government as well as other governments. For example, the U.S. sets price ceilings for certain pharmaceuticals, which are called the federal upper payment (FUL) levels, for Medicaid, which is a State-based program covering the cost of healthcare for certain low-income individuals. Each of the 50 States operates independently under broad federal guidelines, and the federal government and the States share the cost of the program. The FULs are calculated consistent with a statutory formula and based on data submitted by pharmaceutical manufacturers. With few exceptions, these upper limits, plus "reasonable" dispensing fees, are the maximum amount the States can pay for multiple-source drugs.

Private Health Insurance Methods. Since they do not have the authority to set the prices of drugs in the U.S., private health insurers often try to limit drug expenditures by managing the quantity of drugs purchased. Private health insurers, as well as government health systems, use their formulary as leverage in negotiating prices, rebates, and discounts with drug manufacturers and distributors. (A formulary, as mentioned above, is a set of drugs for which a health system or insurer has agreed to pay a portion of the costs; the formulary may also specify contingencies for payment.) A drug manufacturer or distributor may be willing to negotiate these concessions in exchange for favorable placement of their drug on the formulary (i.e. few restrictions on when and how much of the drug may be used and limited or no cost-sharing required for patients).

Addendum to State Initiatives to Promote Cost-Effective Use of Pharmacy Benefits

Recent State Legislative and Executive Activities to Reduce Pharmaceutical Costs within Medicaid and/or State Employee Health Programs

Multi-State Pharmaceutical Purchasing Alliances

WV, LA, MS, MO, NM, SC: led by West Virginia, the coalition unites participating entities to create joint purchasing opportunities, counter detailing and utilization activities, pharmaceutical strategies, and advocacy activities. The working group is divided into two subcommittees, Medicaid and state public employees.

To participate in the coalition, each state must review its own legislative enabling statutes. Several of the states have passed laws authorizing them to join a multi-state or multi- governmental purchasing consortium to purchase pharmaceutical products or other medical services.

Intrastate Pharmaceutical Purchasing Initiatives – Legislative Action Needed

GA, MA, TX: enacted laws to create intrastate multi-agency and multi-program pharmaceutical purchasing pools to gain greater pharmacy price discounts for eligible populations.

o Georgia: consolidated the state's public health insurance programs under one agency to streamline administrative functions and combine health care insurance program purchasing into one unit to maximize purchasing power.

State employee health benefit plan, Medicaid, and SCHIP issued a joint request for proposal (RFP) for a multi-program contract for pharmacy benefit manager (PBM) services (chose Express Scripts).

o Massachusetts: fiscal 2000 budget created a state aggregate or bulk purchasing program to combine senior pharmacy assistance participants, Medicare and Medicaid enrollees, state workers, uninsured and underinsured individuals into one purchasing pool. The state estimated that as many as 1.6 million individuals would be covered, with eventual total savings for individuals and government as high as $200 million. MA has not implemented.

o Texas: June 2001, enacted law to establish a multi-agency bulk purchasing system for prescription drugs. Combines pharmaceutical purchasing for the Departments of Health and Mental Health, state employees, retirees, teachers, prison system and any other agency that purchases pharmaceuticals.

Creates the Interagency Council on Pharmaceuticals Bulk Purchasing, and it would use the state's existing distribution networks, including wholesale and retail distributors, to distribute the pharmaceuticals.

Council is directed to explore various purchasing options, including expanding Medicaid purchasing through federally qualified health centers. The law also includes provisions to require manufacturer and wholesaler price reporting and enforcement mechanisms for the state attorney general. The state estimates approximately $13 million in cost savings for the first two years. The law took effect September 1, 2001.

Preferred Drug Lists/ Governor Appointed Pharmacy and Therapeutics Advisory Boards

FL, LA, KY OR: enacted laws to establish Medicaid Pharmaceutical and Therapeutics Committee to develop preferred drug lists for Medicaid beneficiaries.

o Florida: new law allows Florida to negotiate state supplemental rebates on prescription drugs for Medicaid beneficiaries. Under Florida's new law, the state will continue to participate in the federal

Medicaid drug rebate program, however, the state will now negotiate directly with drug companies to obtain additional rebates.

FL law also requires the state to create a preferred drug list (PDL). All FDA approved drugs with federal rebates are available to Medicaid patients, but those not on the PDL require prior authorization. The PDL was recommended by an appointed committee, which considers both medical effectiveness and cost when determining which drugs to include on the list.

Florida expects to save the state $214 million per year, or about 15 percent of its Medicaid drug budget through its own negotiations.

o Louisiana: established 19 member Medicaid Pharmaceutical and Therapeutics Committee to develop a preferred drug list (PDL) for Medicaid beneficiaries. Physicians must call the Committee to get prior authorization if he/she feels the drug is medically necessary. Committee will be comprised of physicians and pharmacists and may contract with pharmacy schools to handle prior authorization requests.

Louisiana Department of Health will track drug requests to determine any pattern of certain drugs called in for prior authorization. Committee will meet on a regular basis to determine if they need to amend their list. The program is estimated to save the state as much as $60 million annually.

• Kentucky: Governor issued an executive order establishing a Pharmacy and Therapeutics Advisory Committee that will advise the governor and the Cabinet for Health Services on the development and administration of a new drug review process.

The order will allow the state to place certain costly medications on a prior authorization list upon the recommendation of the Committee when the use of the drug presents a financial burden to the state or poses a significant safety issue.

As part of the executive order, the Governor has asked the Cabinet for Health Services to issue an emergency regulation to further reduce pharmacy costs, including:

1. Spell out changes in the drug review process;

2. Require prior authorization for brand name drugs for which there are available generic forms; and

3. Clarify when a drug is a “new” drug and cannot be placed on prior authorization, under terms of existing statute.

The existing Drug Management Review Advisory Board will remain in place and focus on drug utilization review, disease management and provider education.

o Oregon: enacted law directing the Oregon Office of Medical Assistance Programs to create a "Practitioner-managed Prescription Drug Plan" under the Oregon Health Plan. The Oregon Health Plan, which provides insurance coverage to 350,000 low-income Oregonians, will spend nearly $900 million a year on prescription drugs during the next two-year budget.

The Governor also appointed individuals to a Health Resources Commission, who are not subject to legislative confirmation. The Commission is comprised of 15 individuals, including practicing and academic physicians, clinical and academic pharmacists, health care researchers, advocates, and

hospital pharmacists. The Commission is charged with identifying specific classes of drugs.

The new law deletes current state law that prohibits them from developing a drug formulary - a list of preferred drugs bought at discount prices. The law allows the state to select the most effective drug within a group of drugs to be used as a reference drug. Prescription drugs costing more than the reference drug would be reimbursed only at the price of the reference drug under this new plan. The first criterion in developing the reference drug list will be a drug's effectiveness, while the second issue will be cost. The law, however, contains a broad exception whereby a physician could prescribe an alternative drug, to be fully reimbursed, if the physician thought it was medically necessary.

Savings from the formulary are estimated to be about $7 million for the first two years.

Mandatory Generic Substitution/Prior Authorization

ME, MA, WA: executive branch action to limit brand-name drug use within state Medicaid programs and to establish prior authorization.

Maine: the state implemented an aggressive prior authorization program in January and placed 55 medications on the prior authorization list. After implementation of the program, average prescription drug costs per Medicaid beneficiary declined from $52 to $42 per week. In the program's first six months, Maine Medicaid saved $5 million in program costs.

o Washington: Washington State Medicaid plans to implement the Therapeutic Consultation Service program to pressure physicians to prescribe more generic medications by limiting beneficiaries to four brand-name drug products per month. Under the new program, if a patient attempted to fill a fifth brand-name prescription in a month, the pharmacist would contact the physician, who would then have to contact a pharmacist hired by the state for approval.

The state recently signed a contract with the pharmacy benefit manager (PBM), Consultec, to run the program and provide on-call pharmacists six days a week. State officials say the program would save $30 million a year and lead to better patient care.

o Massachusetts: Massachusetts State Medicaid will require Medicaid beneficiaries to use generic drugs when available. Medicaid beneficiaries will be required to use generic medications in place of brand name drugs when they are available except when medical necessity is demonstrated and physicians obtain prior authorization from state administrators.

Under current procedures, the state requires pharmacists to prescribe generic medications to Medicaid beneficiaries unless doctors request brand name medications.

The state estimates that the new system requiring physicians to prescribe generics when available would save the state $10 million in the first year.

Waste and Abuse/Disease Management

TN: launched study of Medicaid pharmacy program to reduce costs.

o Tennessee Waste and Abuse: hired Applied Health Outcomes to conduct an analysis on medications prescribed to TennCare beneficiaries with mental health conditions and to those beneficiaries who are also covered under Medicare (dual eligibles).

TN hired Prudent Rx Inc. to study waste and abuse in the TennCare pharmacy program. Prudent Rx estimates it could save the state $300,000 to $400,000 per month by catching billing errors and outright fraud among pharmacists.

Tennessee Disease Management for Dual Eligibles: carved out pharmacy benefit for dual eligibles (and mental health conditions). Hired the PBM, Consultec, to manage benefit for this population. Although duals only 13 percent of managed care enrollees, account for 35 percent of drug expenditures within program.

TN launched Centers of Excellence initiative in August 2001 to bring together physicians and other leading clinicians within the state to prioritize key disease states that could benefit from implementation of evidence-based education and intervention programs. With the goal of improving quality of health care for TennCare enrollees (including dual eligibles), at least two major disease-based Centers of Excellence will be launched by end of year.

TennCare pharmacy carve out provides benefits for over 200,000 dual eligibles who account for over $60 million per month in prescription costs. To improve efficiency and quality, TN has partnered with Applied Health Outcomes (consulting firm) to develop the program.

As a part of this initiative, TennCare is working with about a dozen pharmaceutical manufacturers to provide disease management services to TennCare beneficiaries (including dual eligibles) and evidence based data on outcomes. State is also working with the National Pharmaceutical Council on this initiative. These manufacturers are funding this part of the initiative. Applied Health Outcomes is liaison between state and pharmaceutical manufacturers.

Cost Sharing

GA, KY: action to propose or implement increased prescription drug cost sharing requirements for Medicaid beneficiaries.

o Georgia: three-tiered copayment structure requires 50 cents for generic drugs, 50 cents for preferred brand-name drugs, and 50 cents to $3 for non-preferred brand-name drugs.

o Kentucky: considering implementing three-tiered copayment structure for Medicaid beneficiaries, which would require payments between $3 and $5 depending on the type of medication.

Combination of Approaches

Many states are combining cost containment strategies.

o Vermont: As part of the New England Tri-State Prescription Drug Purchasing Coalition, Vermont has contracted out its Medicaid pharmacy benefits to a pharmacy benefit manager (PBM-First Health Services). Through the PBM, Vermont will be using a preferred drug list, prior authorization, and physician counter detailing. The PBM will also link directly to the state fiscal agent system to get real time patient prescription information on drug interactions and errors and prior authorization requests. It is estimated that the tri-state initiative will save 10 percent to 15 percent a year on prescription drug costs.

Appendix: Summary overviews of countries

1. China Overview (please see Appendix 3 for additional details on China's health system)

- Use of both Western and traditional Chinese medicine (TCM).
- The National Drug Reimbursement Drug List is separated into two parts: A list (over 315 Western drugs) and B list (over 712 Western drugs) and the rest of TCMs.
- The A list means "Clinic necessary & effective, wide coverage, and lower price." Most of them are local generics with 100% reimbursement; the B list means "Clinic selective & effective".
- State-run, non-profit healthcare institutions in China procure most of the drugs they use through a bidding process centralized at the provincial level.
- Both the essential drug list and medical insurance reimbursement drug list should be established jointly by the Ministry of Labour and Social Security, Ministry of Health, State Food and Drug Administration, and regional health authorities.
- Local governments are responsible only for the procurement of drugs and the contracts signed are usually ambiguous

2. Denmark Overview (please see Appendix 3 for additional details on Denmark's health system)

- Denmark follows the specified time limits set out in the European Community legislation, i.e., the handling of an application takes a maximum of 210 days for national market authorisation.
- Pan-Country purchasing through AMGROS, a politically run organisation, which is owned by the regions. Its purpose is to create economies of scale and administrative savings by consolidating the purchase of pharmaceuticals in one place.
- The main task at Amgros is to ensure that the public hospitals in Denmark always have the necessary pharmaceuticals available - and are always purchased at the lowest possible price. AMGROS ensures the regions make an annual saving of DKK 1.3 billion, through tenders and bulk purchasing.
- Provincial hospitals buy from AMGROS through a computer system, acting as a third party buyer.
- AMGROS ensures the regions make an annual saving of DKK 1.3 billion, through tendering and bulk purchasing
- The handling of an application for national market authorisation is divided into four phases which are (1) start-up phase, (2) assessment phase, (3) follow-up phase and (4) closing phase.

  Implications for PCPA: This type of a bulk purchasing arrangement is currently not being actively contemplated by PCPA and would require significant policy changes to be implemented

3. Finland Overview (please see Appendix 3 for additional details on Finland's health system)

- The responsibility for organising health care lies with the approximately 400 municipalities, who organize and/or purchase most of the health services they need with most financing via local taxation.
- Universal health care is available to all citizens in Finland. The system is administered at the municipal level, and financing occurs through state and municipal taxation. Public health care covers in-patient medication.
- The National Health Insurance Scheme (NHIS) covers part of the costs of out-patient physician visits and out-patient pharmaceuticals. Out-patient medicines are sold through privately owned pharmacies.
- Public sector procurement in Finland is decentralized. In the in-patient sector hospital districts, joint municipal authorities for primary health care and municipalities collaborate on the practical level for the procedures and organisation of tendering. Purchases are made at district level (although there is bulk purchasing between a few districts): hospital districts work with municipal authorities to invite public tenders.

4. New Zealand Overview (please see Appendix 3 for additional details on New Zealand's health system)

- There are 20 District Health Boards that oversee the 46 Primary Health Organizations established throughout the country.
- Mixed public-private system
- Pharmaceutical Management Agency (PHARMAC) is the New Zealand Crown agency that decides, on behalf of District Health Boards, which medicines and related products are subsidised for use in the community and public hospitals.
- Medsafe is the New Zealand Medicines and Medical Devices Safety Authority, responsible for the regulation of medicines and medical devices in New Zealand.
- Deals are single supplier; hence, New Zealand can experience the issue of supply problems.

5. Singapore Overview (please see Appendix 3 for additional details on Singaporee's health system)

- Non-modified universal healthcare system, i.e., Medisave
- Procurement of drugs is done through a tendering process by SingHealth
- There are currently over 600 drug preparations in the Standard Drugs List (SDL) with over 487 in SDL 1 and over 101 in SDL 2.
- A key principle of Singapore's national health scheme is that no medical service is provided free of charge, regardless of the level of subsidy, even within the public healthcare system. This mechanism is intended to reduce the overutilization of healthcare services.
- To support Singapore's Ministry of Health and the Drug Advisory Committee (DAC) in the

management of the SDL, a specialist support unit, the Pharmacoeconomics and Drug Utilization Unit (PEDU) was established under the Centre for Drug Administration (CDA), to provide technical and secretariat support to the DAC. PEDU is fully funded by MOH to carry out on-going review and revision of the SDL.

6. Switzerland Overview (please see Appendix 3 for additional details on Switzerland's health system)

- Federal state made up of 26 states known as cantons. Health care is the responsibility of three levels of government: the federal government, the cantons and the communities.
- Mandatory private social health insurance system with unrestricted access to health care and free choice of providers.
- Decision time targets for approval of drug listing procedures are consistent with international standards: 200 days for ordinary procedures and 130 days for fast-track procedures.
- The federal government sets the maximal allowable public price for drugs in the Positive Drug List
- Negotiations are handled by each individual insurer through wholesalers.
- The distribution margin is also regulated for the drugs listed on this specialty list, and set at the level of the ordinance. This distribution margin is to be shared between wholesalers and pharmacists, who can negotiate individually how the margin is distributed

7. United Kingdom (UK) Overview (please see Appendix 3 for additional details on UK's health system)

- Primary Care Trusts (PCTs) are responsible for delivering health care and health improvements within a local area. The PCTs are grouped into regional Strategic Health Authorities (SHAs); these groups help develop local National Health Service (NHS) strategy and provide a link between the PCTs and the national Department of Health (DH).
- Drug formularies are developed locally by the PCTs and NHS Trusts. The PCTs adapt these formularies to contain costs and remain in budget.
- The NHS PCTs purchase care from NHS acute trusts. The contract price includes the full package of care including the purchase of medicines.
- The NHS list price for branded medicines agreed under the Pharmaceutical Price Regulation Scheme (PPRS) and for generic medicines in the Drug Tariff is the reimbursement price in primary care. In secondary care, hospitals may be able to negotiate a discount.
- The price of drugs is negotiated or agreed by the NHS Business Services Authority and what's difficult to control is the prescribing of branded drugs over cheaper generic ones. As prices are negotiated centrally, strategies have focused on non-drugs expenditure of around £18bn annually – particularly on consumables.

Significant reform to the above has occurred in the past three months via the PPRS.

The following are the most recent changes to the UK system:

- A ceiling on how much NHS drugs bill can grow from 2014-2019
- A special austerity deal:
    1. The biggest change in the PPRS comes in the form of 'austerity commitment' from industry (termed as Allowed Growth Rate of Measured Spend). The industry as a whole has agreed to keep the growth the branded medicines bill at 0% for 2014 and 2015, and with modest growth in later years (1.8%, 1.8% and 1.9%). If the NHS spends more, industry will be paying back to help balance the books.
    2. The industry-wide commitment is underpinned by quarterly payments from companies on their net sales (with some differences for small companies and exemptions). Companies will be paying back 3.74% in 2014, and estimated payments in percentage terms are 7.13%, 9.92%, 9.92%, and 9.92% for 2015-18, respectively.
- Retention of traditional PPRS, including free pricing at launch
- Some elements of the PPRS remain the same and include free pricing at launch, profit control and financial returns to the DH.
- **Value-Based Pricing**
  The agreement also has some elements that relate to Value-Based Pricing (VBP). In practice, the VBP will turn into a wider assessment of value undertaken by the National Institute for Health and Care Excellence (NICE) in England and Wales. The new PPRS says:

    1. There will be no change to the threshold range for cost effectiveness used by NICE
    2. NICE cannot change the Terms of Reference (ToR) on VBP set for them by the DH without publicly consulting first. The ToR cover Burden of Illness (BoI) and Wider Societal Benefits (WSBs)
    3. No role for NICE in price setting.

Access to medicines

Access to medicines is now more about embedding the efforts of those involved in delivering on Innovation, Health and Wealth (IHW) but features like Patient Access Schemes stay, too. The IHW is about accelerating the diffusion of innovation in the NHS, and for medicines it has led to the Innovation Scorecard to explore variation in uptake of medicines and requirements for local formularies to include positive appraised medicines. The NHS England will be held to account by DH too on access to medicines, reflecting the wider changes to the NHS since the last PPRS was negotiated.

PPRS alternative – the Statutory Scheme

Many companies will prefer to join the voluntary PPRS simply because the alternative, the Statutory Scheme for Branded Medicines, includes a 15% price cut for 2014. And with the option for Government to change that deal every year, more cuts could come down the line. Both Industry and Government have highlighted the 5-year stability of the latest PPRS.

8. United States of America (USA, U.S.) Overview (please see Appendix 3 for additional details on USA's health system)

The reimbursement system in the U.S. is based on a mixed public/private third-party payment system whereby government, employers, and individuals share the cost of care. Premiums are paid to private insurance companies for private coverage either by individuals or employers. Government coverage provided at federal (Medicare, Department of Defense, Bureau of Indian Affairs) and state levels (Medicaid) to statutorily defined populations (elderly, poor, disabled, veterans, etc.). Many private insurers also cover Medicare and Medicaid populations financed by the government.

As one of the fastest growing portions of healthcare costs in the U.S., drug expenditures have been a matter of concern in the U.S. for many years. The U.S. has a health care system involving a combination of private and public payers adopting a variety of pharmaceutical reimbursement policies. The private insurance companies may negotiate drug prices, rebates, and drug-volume discounts with pharmaceutical manufacturers. The three largest U.S. government purchasers of pharmaceuticals – Medicare, Medicaid, and the Department of Veterans Affairs (VA) – use a mixture of methods, including reimbursement-rate setting, price ceilings, negotiated prices, discounts, and rebates, as well as other cost and utilization-management tools. These are further reviewed in Appendix 3.

USA Bulk Purchasing

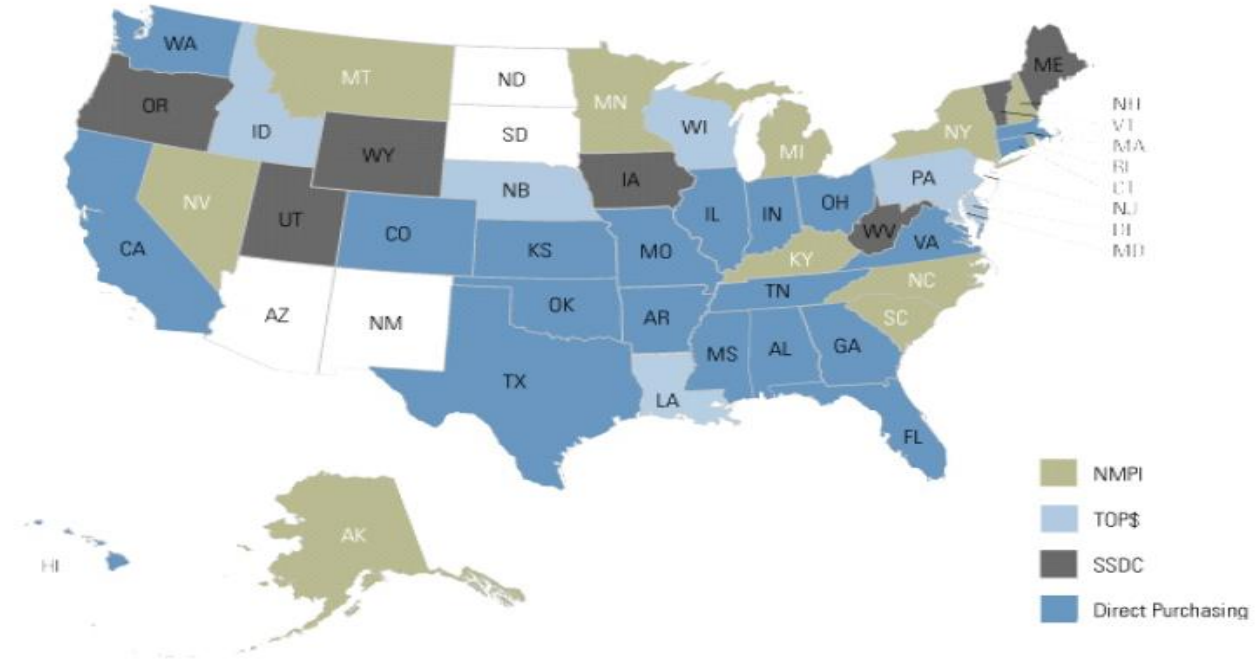
American policymakers are confronted by the increasing costs of pharmaceuticals and the challenges of ensuring access to medicines and quality of care. Rising costs are attracting growing attention to bulk purchasing agreements in the U.S. In 1999, the Massachusetts state government authorized a statewide bulk purchase plan, and since that time an increasing number of states and other entities have explored aggregate pharmaceutical purchasing. As of early 2012, five multi-state bulk buying pools are in operation. Numerous single state initiatives are also in effect.

The programs in operation are:

1. The National Medicaid Pooling Initiative (National Medicaid Buying Pool or NMPI or NMBP)

2. Top Dollar Program (TOP$)
3. The Sovereign States Drug Consortium (SSDC)
4. The Northwest Prescription Drug Consortium
5. The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)

Program	Program Adminster
The National Medicaid Pooling Initiative (National Medicaid Buying Pool or NMPI or NMBP)	Magellan Medicaid Administration, Inc./Provider Synergies
Top Dollar Program (TOP$)	Provider Synergies
The Sovereign States Drug Consortium (SSDC)	State-administered multi-state Medicaid supplemental drug rebate pool, this program is entirely owned by the participating states
The Northwest Prescription Drug Consortium	Oregon-based pharmacy benefits management company
The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)	State of Minnesota



Source: Kittridge, Rivera, Coyle, and Zucarelli, 2011: 28.

Figure 1: Various bulk purchasing plans in US

Country	***Australia***	***Canada***
Primary body responsible for assessing new (outpatient) drugs for funding/ subsidy under the statutory system	Pharmaceutical Benefits Advisory Committee (PBAC)	Canadian Expert Drug Advisory Committee (CEDAC)
Summary of process	PBAC requires a value for money case for each new drug, which is then subject to assessment by HTA organisations contracted by PBAC. Decisions on drugs and devices for use in public hospitals are made by state governments with some having established advisory committees and working groups to assess requests to use new medicines in hospital settings.	CEDAC considers reviews received through the Common Drug Review (CDR) at the Canadian Agency for Drugs and Technology in Health (CADTH); it makes recommen- dations for listing of new drugs to partici- pating federal/ provincial/territorial drug plans (except Québec). Hospitals determine their formularies through their Pharmaceutical and Therapeutics Committee.
Principal role of the assessing body: advisory or regulatory[2]	Advisory: PBAC makes recommendations to the Government	Advisory: CEDAC makes formulary listing recommendations for Canada's publicly funded plans
Positive and/or negative list	Positive list: Pharmaceutical Benefits Scheme (PBS)	Positive lists (formularies) for each Canadian jurisdiction
Arrangements for co-payment for pharmaceuticals: ambulatory/out- patient sector	General beneficiaries: AUD 31.30 Concessional beneficiaries: AUD 5.00	A variety of income- related deductibles and co-payments
Arrangements for co-payment for pharmaceuticals: in-patient sector	No co-payment required	No co-payment required
Time from licensing to regulatory approval for reimbursement under the statutory system	Around 6 months	Between 3 and 4 months (94 to 124 days)
Is cost- effectiveness, an overt criterion for the decision whether to list a drug for reimbursement/ subsidy under the public system?	Yes PBAC requires a 'value for money' case for each new drug. In addition, PBAC takes into account: the importance of the clinical area; the availability of alternative treatments; the likely effect of listing on the health system and other therapeutic activities; and the investment of the sponsor in primary research	Yes However, processes and rules for formulary listing differ among provinces and territories. Except for Québec, all Canadian jurisdictions consider CEDAC's recommendations for their decisions. Economic considerations range from simple budget impact analysis to more elaborate cost- effectiveness studies provided by the manufacturer
Examples of drugs that have been excluded from reimbursement/ subsidy under the statutory system	Sunitinib (*Sutent*) for renal cancer Erlotinib (*Tarceva*) for NSCLC Cetuximab (*Erbitux*) for colorectal cancer Bevacizumab *(Avastin*) for colorectal cancer	Sunitinib (*Sutent*) for metastatic renal cell carcinoma
Nature of funding of the health system (% of public funding)[3]	Federal taxes (68%)	Provincial, territorial and federal taxation (70%)
Total expenditure on health in % of GDP[3]	9.5	9.8
Total expenditure on pharmaceuticals (in % of total health expenditure)[3]	13.3	17.3
Public expenditure on pharmaceuticals (as % of total expenditure on pharmaceuticals)[3]	57.6	38.4

Country	***Denmark***	***Finland***
Primary body responsible for assessing new (outpatient) drugs for funding/ subsidy under the statutory system	Danish Medicines Agency (DKMA)	Pharmaceutical Pricing Board (PPB)
Summary of process	DKMA decides on information received by the Reimbursement Committee (within DKMA). The Danish Centre for Health Technology Assessment (DACEHTA) is responsible for assessments of new drugs (especially new cancer drugs). Hospitals have one or more Drug and Therapeutic Committees which determine the hospital's formulary lists.	The PPB is responsible for decisions on the reimbursement status of pharmaceuticals and for confirming wholesale prices Hospitals decide independently on their drug formularies on the basis of therapeutic and economic effectiveness.
Principal role of the assessing body: advisory or regulatory[2]	Regulatory	Regulatory
Positive and/or negative list	Positive list	Positive list
Arrangements for co-payment for pharmaceuticals: ambulatory/out- patient sector	i) General reimbursement for prescription-only medicines and over-the-counter drugs ii) According to 4 reimbursement rates: 50%, 75%, 85% and 100% of the retail price	Basic refund/ lower special refund: 58% & 28% co-payment. Higher special refund/ additional refund: EUR 3 and 1.5
Arrangements for co-payment for pharmaceuticals: in-patient sector	No co-payment required	No co-payment required
Time from licensing to regulatory approval for reimbursement under the statutory system	Less than 3 months (longer if the Reimbursement Committee is consulted more than once)	6 months (180 days)
Is cost- effectiveness, an overt criterion for the decision whether to list a drug for reimbursement/ subsidy under the public system?	No A health economic analysis may be enclosed by the pharmaceutical companies to demonstrate to the Reimbursement Committee the cost-effectiveness of a new drug, but this is not mandatory. A health economic analysis as part of the reimbursement decision-making is only relevant for drugs that contain a new active agent.	Yes PPB's decision- making is based on the therapeutic benefit, patient benefit, cost- effectiveness and budget impact
Examples of drugs that have been excluded from reimbursement/ subsidy under the statutory system	Not known	Citalopram (*Cipramil)* because of cheaper generic alternatives
Nature of funding of the health system (% of public funding)[3]	Central and local (municipal) taxes (84.1%)	Central and local (municipal) taxes plus national health insurance contributions (78%)
Total expenditure on health in % of GDP[3]	9.2	7.4
Total expenditure on pharmaceuticals (in % of total health expenditure)[3]	9.0	16.3
Public expenditure on pharmaceuticals (as % of total expenditure on pharmaceuticals)[3]	56.3	56

Country	***New Zealand***	***Switzerland***
Primary body responsible for assessing new (outpatient) drugs for funding/ subsidy under the statutory system	Pharmac Board	Federal Office of Public Health (OFSP)
Summary of process	Pharmac's decisions are informed by the Pharmacology and Therapeutics Committee (PTAC). Hospital Pharmaceuticals Assessment Committee informs Pharmac on in-patient drugs.	A drug may be included in the positive lists if (1) it is licensed by Swissmedic, (2) it is effective & appropriate, and (3) it provides value-for- money. A drug is considered value-for- money when it produces a given therapeutic effect at the lowest cost.
Principal role of the assessing body: advisory or regulatory[2]	Regulatory	Regulatory
Positive and/or negative list	Positive list (Pharmaceutical Schedule)	Positive list
Arrangements for co-payment for pharmaceuticals: ambulatory/out- patient sector	If prescribed by a Primary Health Organisation practitioner the maximum co-payment is NZD 3.The remainder have a max. of NZD 15 for 3-month's supply/ Lower levels apply, depending on age & income of patients	Insured persons pay a fixed annual amount (franchise) plus 10% of further costs (share). The sum of the franchise and the share is limited by a fixed maximum per year
Arrangements for co-payment for pharmaceuticals: in-patient sector	No co-payment required	A small contribution must be paid towards hospital costs in some cases
Time from licensing to regulatory approval for reimbursement under the statutory system	Not known	Less than 5 months
Is cost- effectiveness, an overt criterion for the decision whether to list a drug for reimbursement/ subsidy under the public system?	Yes An additional 8 criteria are taken into consideration by Pharmac when deciding on a new drug	Yes (as defined by the principle of 'value-for- money'). A new drug has to be effective appropriate and value for money in order to be included in the positive list. Effectiveness is the most important criterion
Examples of drugs that have been excluded from reimbursement/ subsidy under the statutory system	Sunitinib (*Sutent*) for renal cancer Bevacizumab (*Avastin*) Erlotinib *(Tarceva)* for NSCLC Ranibizumab (*Lucentis*)	Not known
Nature of funding of the health system (% of public funding)[3]	General budget for health care: Central taxes (78.1%) Accident Compensation Scheme (ACC): Contributions plus central taxes	Mandatory health insurance, individuals' out of pocket payments, and State (federal, cantonal, regional) financing (16.2%)
Total expenditure on health in % of GDP[3]	8.5	11.5
Total expenditure on pharmaceuticals (in % of total health expenditure)[3]	12	10.4
Public expenditure on pharmaceuticals (as % of total expenditure on pharmaceuticals)[3]	64	67.2

Country	Australia	Denmark	Finland
Name of body	Pharmaceutical Benefits Advisory Committee (PBAC)	Danish Medicines Agency (DMA)	Pharmaceuticals Pricing Board (PPB)
Role in reimbursable drug list development	PBAC is responsible for providing advice to the Minister of the Department of Health and Ageing regarding which drugs to include on the Schedule of Pharmaceutical Benefits (SPB), the reimbursable drug list. Specifically, it recommends maximum usage quantities and restrictions on prescribing indications. It also informs the Pharmaceutical Benefits Pricing Authority (PBPA) of a drug's comparability with existing alternative therapies and its cost-effectiveness. For example, when a drug is proven to be substantially more costly than an alternative therapy, PBAC recommends that it only be offered to patients for whom a significant improvement in efficacy or reduction in toxicity over the alternative therapy is expected. PBAC's membership includes health economists, pharmacists, general practitioners, clinical pharmacologists, specialists in clinical medicine, and consumers. In addition, it has 2 sub-committees: the Economics Sub-Committee (ESC) and the Drug Utilization Sub-Committee (DUSC). The ESC assesses and interprets economic evaluations for drugs under review by the PBAC and establishes criteria for their submission. The DUSC collects and analyses data on drug utilization trends in Australia and compares them with those in other countries. It also assists with generating information regarding the rational prescribing and use of drugs.	The DMA, under the authority of the Consolidated National Health Security Act, is responsible for all pharmaceutical legislation including approval of new drugs for market, determination of the reimbursement status (general or individual) of all drugs, and management of clinical trials. The Reimbursement Committee advises the DMA on the potential therapeutic benefits of certain drugs. This committee, comprised of 7 general practitioners, is appointed by the Minister of the Interior and Health.	The PPB, under the auspice of the Ministry of Social Affairs and Health, determines the reimbursement status of drugs. This is accomplished through its approval of a reasonable wholesale price (i.e., the maximum price at which the drug may be sold to pharmacies and hospitals) for each drug. All drugs whose reasonable wholesale prices have been accepted by the PPB become reimbursable under the Sickness Insurance Act. The PPB is comprised of 7 Ministry of Social Affairs-nominated members and their deputies. All members are at least Master's level graduates of the medical, pharmaceutical, legal, and economic disciplines. In addition, 2 represent the Ministry of Social Affairs and Health and 2 are from the national Sickness Insurance Institution. The remaining 3 members represent the National Agency for Medicines, the National Research and Development Centre for Welfare and Health, and the Ministry of Finance.
Criteria for reimbursement	Before a drug is assessed by PBAC, it must be registered by the Therapeutic Goods Administration, indicating that it has met acceptable levels of quality, safety, and efficacy, and, thus, may be marketed in Australia. PBAC then makes listing recommendations based on the effectiveness, cost-effectiveness, and the clinical place of a drug compared with alternative therapies. It considers whether the drug is (1) needed for the prevention or treatment of significant medical conditions not already covered or inadequately covered by drugs on the existing SPB *and* is of acceptable cost-effectiveness, (2) more effective and/or less toxic than a drug already listed for the same indication(s) *and* is of acceptable cost- effectiveness, or (3) at least as effective and safe as a drug already listed for the same indications and is of similar or better cost-effectiveness. As mandated by the Minister, PBAC also reviews (4) the community's need for the drug, (5) the setting in which the drug would be administered (since Australia's Pharmaceutical Benefits Scheme was created to serve community-based patients, drugs for in-hospital use are given low priority), and (6) the significance of the condition for which the drug is indicated (drugs for minor conditions are given low priority). In general, PBAC does not recommend listing: (1) a fixed combination of drugs, (2) a drug that may create abuse or dependence problems, or (3) a drug intended to treat an individual patient whose response or need is viewed as unique. PBAC may also decide to remove a drug from the PBS if (1) a more effective or equally effective *and* less toxic drug becomes available, (2) subsequent evidence indicates that the drug's effectiveness is not satisfactory, (3) subsequent evidence indicates the drug's toxicity or potential for abuse outweighs its therapeutic value, (4) the drug is either no longer used or available, or (5) when compared with alternative therapies, the drug is no longer cost-effective.	Reimbursement decisions are guided by the following principles: (1) the drug must have a proven definite and valuable therapeutic effect for a defined indication, and (2) the price of the drug must be proportionate to its effect. Further, reimbursement will not be granted if : (1) the drug requires special examination and diagnosis, (2) there is a risk of the drug being used outside of its approved indication, (3) the drug's proposed clinical effect has not been documented, (4) the drug will likely be used as the first line of treatment, regardless of whether or not evidence supporting such use exists, (5) the drug has a high potential for abuse, and (6) the patient is not able to self-administer the drug.	Decisions regarding what constitutes a drug's reasonable wholesale price are based on assessments of its cost effectiveness (i.e., its costs relative to its expected benefits for the patient and for total expenditures on social and health care services). The PPB also considers statements submitted by the Social Insurance Institution which address the fairness of the proposed wholesale price in terms of the overall Sickness Insurance Scheme.
Instruments/information used in decision-making	PBAC's recommendations are mainly based on a review of the economic analysis that must accompany each drug submission. The type of economic analysis needed depends upon the category of drug for which listing is sought: Category 1 – proposed drugs offering either greater effectiveness and similar or less toxicity than the alternative therapy, similar effectiveness but less toxicity, or significantly greater effectiveness but more toxicity; Category 2-proposed drugs offering similar levels of effectiveness and toxicity to the alternative therapy; and Category 3-proposed drugs which are less effective but also less toxic than the alternative therapy. For Category 1 drugs, cost-effectiveness analysis (CEA) or cost-utility analysis (CUA) is indicated. Category 2 drugs require a cost-minimization analysis. Since those in Category 3 involve clinical and cost trade-offs, an evaluation of adverse outcomes is requested. In addition, PBAC asks that data from "head to head" randomized trials (which directly compare the proposed drug with the alternative therapy) be provided, where available.	None stated. However, the Institute for Rational Pharmacotherapy, whose mandate is to promote rational drug use through the production of objective information and guidelines on drugs for which there is high pharmacotherapeutic or economic concern, supports reimbursement decision-making.	Applications must include a comprehensive economic evaluation of the costs of the drug and the benefits expected to be gained by its use relative to those of the alternative therapies. Analyses that, applying the same outcome measurements, present comparisons of all of the drug's health effects (both positive and negative) and direct health and societal costs with those of the alternative therapies are required. The compared therapies yielding the greatest benefit relative to available resources must also be provided. In addition, applications must include an estimate of the sales volume, expected number of users, grounds for reimbursement in other European Economic Area countries, and other brand names under which the drug is marketed and their respective prices.
Review processes	Applications for listing new drugs may be submitted to PBAC by manufacturers, medical bodies, health professionals, or private individuals. Upon receiving an application, PBAC distributes copies to all members within each of the following three committees for their independent review: (1) The Pharmaceutical Evaluation Section (PES) of the Department of Health and Family Services, (2) The ESC, and (3) PBAC, itself. The PES and ESC then convene to discuss the application and complete separate comprehensive evaluations. These evaluations, which include a summary of therapeutic claims, evidence, and analyses, are forwarded to PBAC, who then uses them as the basis for its advice to the Minister. If deemed necessary, PBAC may seek expert advice from other relevant professional bodies and/or specialists. In cases where PBAC recommends to the Minister that a new drug be listed and he/she accepts this recommendation, the submission is sent to the Pharmaceutical Benefits Pricing Authority, who negotiates the prices of drugs listed on the PBS. The PBPA then notifies the Minister. PBAC informs applicants of its decisions within 15 days of the meeting at which the application was submitted for consideration.	Once a prescription drug has received marketing approval, the DMA considers it for reimbursement. Based on the advice of the Reimbursement Committee and the criteria listed above, the DMA determines the drug's reimbursement status.	Applications or cases are presented at PPB meetings by the Senior Pharmaceutical Officer of the Secretariat to the PPB or the pharmaceutical officers under the supervision of the Secretary General. During its deliberations, it reviews all of the health-economic aspects of the drug, as well as the associated manufacturing and R&D costs. It then consults with the Social Insurance Institution to assess the potential impact of a proposed wholesale price on the Insurance Scheme.
Formal appeals mechanism	None stated.	None stated.	None stated.
Health Care Financing	A largely government funded national system of health care, "Medicare," provides universal access to all public hospital services and a comprehensive range of other medical services, including primary health care, vaccinations and prescription pharmaceuticals in Australia. Limited private insurance is available and covers a range of in-hospital and ancillary medical services, such as physiotherapy and dental services.	Denmark provides healthcare coverage to all citizens through its national health insurance system administered at the regional level. Health care services are financed through regional taxation and patient co payments. In general there is free access to all hospital services as well as visits to general practitioners. Private insurance is also available for purchase by Danish citizens. Around 1.7 million citizens are members of the private insurance company "Danmark", that predominantly covers dentist services and pharmaceuticals. A large proportion of co-payments are covered by this supplementary private insurance.	Universal health care is available to all citizens in Finland. The system is administered at the municipal level, and financing occurs through state and municipal taxation. Public health care covers in-patient medication. The National Health Insurance Scheme (NHIS) covers part of the costs of out-patient physician visits and out-patient pharmaceuticals. Out-patient medicines are sold through privately owned pharmacies.

Country	New Zealand		United Kingdom		Switzerland
Name of body	Pharmacology and Therapeutics Advisory Committee (PTAC)	Pharmaceutical Management Agency (PHARMAC)	Department of Health (DH), National Assembly of Wales (NAW)	National Institute for Clinical Excellence (NICE)	Federal Office of Public Health (OFSP)
Role in reimbursable drug list development	PTAC serves as an expert advisory committee on pharmaceuticals and their benefits, making recommendations to PHARMAC regarding applications for the listing/de-listing and restricting/de-restricting of individual drugs on the Pharmaceutical Schedule. It also provides advice on the type of information that should be included in applications for listing and, upon PHARMAC's request, the definition, removal, or amendment of entire groups or sub-groups of drugs on the Schedule. In addition, it periodically monitors and reviews policies adopted by PHARMAC for managing drugs, and then suggests any necessary modifications. PTAC consists of clinicians, who either applied directly or were nominated by a professional medical body, with expertise in clinical pharmacology, internal medicine, and general practice. When there is limited time or a need for specialist advice, sub-committees appointed by the Chairperson of PTAC or PHARMAC are created. These subcommittees report to either PTAC or PHARMAC, depending on which of the two bodies initiated their appointment.	PHARMAC manages the government's expenditure on pharmaceutical subsidies. Therefore, its activities include (1) establishing criteria for access to subsidized pharmaceuticals, (2) controlling amendments to the Pharmaceutical Schedule (e.g., listing new drugs, modifying guidelines or restrictions on the prescribing of listed drugs, changing subsidy levels, revising rationale used to classify drugs into therapeutic groups and/or sub- groups, de-listing individual or groups of drugs, and changing packaging and/or brand names), (3) negotiating subsidization of drugs with their manufacturers, and (4) promoting appropriate prescribing and best practice initiatives. In addition, PHARMAC maintains a Consumer Advisory Committee who seeks and receives input from consumers (i.e., the public and patients).	Most ''licensed'' drugs (i.e., those which have met the safety, quality, and effectiveness standards required by the Medicines and Healthcare Products Regulatory Agency) are assessed at local National Health Service (NHS) levels to determine whether or not they will be subsidized by organizations within them. However, for certain drugs, the DH and NAW may decide that a full, systematic assessment is necessary. This decision is based on consultations with relevant patient and professional bodies and manufacturers of the drug, as well as recommendations provided by an Advisory Committee on Topic Selection (ACTS) and the Joint Planning Group (JPG). The ACTS is responsible for reviewing requests pertaining to all types of health care technologies (e.g., drugs, medical devices, diagnostic techniques, surgical procedures, etc.). Once a drug is selected, the Minister refers it to NICE for appraisal. The ATCS comprises all of NICE's stakeholder groups: the DH (7 members), NICE (4 members), NAW (1 member), NHS (4 members), health care professionals (4 members), patients (4 members), universities (2 members), and industry (2 members). It may appoint additional health care professionals ''for the day'' to advise on technologies outside of the expertise area of committee members. The Joint Planning Group is comprised of senior DH, NAW, and NICE officials who examine the feasibility of assessing proposed technologies.	NICE was established to provide clear national guidance on the use of health technologies and, in doing so, standardize access to care across the country. Accordingly, it appraises the clinical effectiveness, cost-effectiveness, and wider NHS implications of new and existing drugs submitted by the DH/NAW for which there is uncertainty over their value or inter-jurisdictional variation in their availability. All guidance issued by NICE must be adopted by local NHS organizations within three months of its publication.(i.e., the National Health Service must fund all drugs recommended by NICE). All appraisals are carried out by the NICE Appraisal Committee who must estimate the net costs and benefits associated with a drug. This statutory committee includes 39 Standing Members who are specialists in clinical medicine, general practitioners, nurses, health economists, clinical pharmacologists, pharmacists, NHS managers, biostatisticians, epidemiologists, industry representatives, and heads of patient-focused groups.	The FOPH is the final pricing & reimbursement decision maker. FOPH decisions are based on FDC recommendation and in line with the HIA (Health Insurance Act) and its regulations. International and therapeutic benchmarking are used to set initial drug prices. The FOPH reevaluates pricing & reimbursement of drugs every three years and after patent expiry. In addition reevaluation also takes place in case of new indications or changed limitations.
Criteria for reimbursement	Although not mandatory, drugs submitted for listing should have already gained marketing approval from MedSafe, New Zealand's medicines and medical devices safety authority. Recommendations by PTAC and decisions by PHARMAC concerning a specific drug or drug group are based on consideration of the following Decision Criteria: (1) the health needs of people eligible for government-funded drug coverage within New Zealand, particularly those of the Maori and Pacific people, (2) clinical benefits and risks related to the drug or drug group, (3) availability and suitability of existing drugs, therapeutic medical devices, and related products, (4) the cost-effectiveness of the drug or drug group compared with that of other health care services, (5) the potential budgetary impact of changes to the Pharmaceutical Schedule on the overall health budget, (6) direct costs to health service users, (7) compliance with government-defined priorities for health funding, and (8) other criteria it deems appropriate. The extent to which recommendations take into account each criterion is determined by PTAC.		Criteria/questions considered by the DH and NAW when selecting drugs, as well as other technologies, for appraisal include the following: (1) could guidance promote a significant improvement in patient care, given available resources, (2) will NICE be able to add value by issuing guidance (i.e., is there a sufficient evidence base and/or a reason to believe that the absence of guidance will lead to variation in access to treatment), (3) would the most appropriate form of guidance consist of an appraisal, clinical guideline, or both, and (4) for new drugs, ''does the balance of advantage for patient care lie with appraisal at the time it's launched'', taking into account equity of access in the absence of guidance and the quality of available evidence?	As directed by the Secretary of State, NICE must consider all of the clinical benefits of a drug, including its impact on disease incidence and prevalence, mortality, and quality of life (e.g., relief of pain and disability), along with all of the associated costs, thereby ensuring that its recommendations promote the effective use of NHS resources. NICE also takes into account the degree of clinical need of affected patients, any clinical priorities of the Secretary of State and the NAW and resources likely to be available, and the ''long-term interests of the NHS in encouraging innovation of good value to patient.	To be reimbursed by basic health insurance coverage, drugs have to be listed in the *"Liste des spécialités"*, established by the Federal Office of Public Health. Reimbursement decisions are informed by the advice of the Federal Drug Commission. The FOPH makes the final decision on reimbursement based on the FDC recommendation. Basically, a new drug must be effective, appropriate and cost-effective to be listed in the positive list (SL). Public promotion is not allowed for SL-listed drugs. Efficacy and appropriateness are mostly based on SATP assessment; cost-effectiveness (value-for money) considers both international benchmarking with Germany, UK, Denmark, the Netherlands, France, Austria and therapeutic benchmarking (comparative effectiveness e.g. daily treatment costs). An innovation reward of up to 20% may be granted during the patent protection period.
Instruments/information used in decision-making	When developing its recommendations, PTAC reviews studies of clinical outcomes, cost-effectiveness, and comparisons with alternative therapies included in applications for reimbursement.	PHARMAC relies primarily on cost-benefit information, in particular, data from cost-utility analyses, to evaluate new drug applications. However, it also considers pharmacological, therapeutic, epidemiologic, price, and market information.	Information describing the burden of disease/condition for which the drug is indicated, other available interventions, and the state of the evidence base is used. General developments in the therapeutic area, addressing questions such as, is it rapidly changing, is relevant service provision well developed, and is there a shared understanding of appropriate endpoints for treatment?, are also reviewed. This information is obtained through commissioned briefing notes (based on published literature) and stakeholder consultations.	NICE recommendations are based on a review of clinical and economic evidence. Therefore, applications should contain data on final clinical outcomes (i.e., life years gained and changes in quality of life) rather than intermediate ones (i.e., events avoided or changes in physiological measures). Since NICE is concerned with issues of clinical effectiveness as opposed to clinical efficacy, data from prospective, randomized controlled trials, conducted in a naturalistic health care setting that imposes minimal restriction on the normal decision-making processes of health care professionals and patients, should be presented, where possible. It is recommended that economic evaluations submitted include assessments from the perspective of NHS and Personal Social Services decision-maker. Depending on the drug and its indications, cost-effectiveness or cost-utility analysis should be used. To assess the ''wider NHS impact'' of the drug, a budget impact analysis, which considers varying diffusion rates over on a 3-5 year period, should be provided.	The principles and process for inclusion in the positive list of medicines are established by ordinances issued by the Federal Council (OAMaL) and the Department of Interior (OPAS). According to the OAMaL, a medicine must fulfill the following conditions to be included in the positive list (article 65): it must be approved by Swissmedic; be ''effective, appropriate and value-for-money (*"économique"*). The assessment of effectiveness must be based on controlled clinical trials for allopathic drugs (OAMaL art. 65). The Drug Commission relies on Swissmedic's work to assess effectiveness but may require other data (OPAS, art. 32). A drug is considered to be value-for-money when it produces a given therapeutic effect at the lowest possible cost (OPAS, art. 34-1). To evaluate if a drug is ''value-for-money'', the OFSP considers the manufacturer's proposed price against ''its manufacturer's price abroad; its therapeutic effectiveness compared to other medications with identical indications or similar effects; its daily car period, should be provided.into account each criterion is determined by PTAC.2 members), and industry (2 members). It may appoint additional health care professionals ''for the day'' to advise on technologies outside of the expertise area of committee members. The Joint Planning Group is com
Review processes	Applications for amendment to the Pharmaceutical Schedule (e.g., listing, de-listing, or re-classification) are submitted directly to PHARMAC. The Chairperson and Medical Director of PHARMAC, as well as the PTAC Secretary, review each application and determine whether (a) it should go directly to PTAC, (b) it should be evaluated by an appropriate sub-committee prior to PTAC, or (c) relevant medical groups and interested parties should be invited to outline issues related to the application (e.g., a drug's benefits over currently funded treatments) which, in turn, will be considered by PTAC or a Sub-committee when it conducts its review. In cases where the application is regarded as complex, PHARMAC may choose to use a two-stage process involving two meetings of PTAC. During the first meeting literature provided by the manufacturer or obtained from independent searches is critically appraised. If PTAC deems the application ''worthy of further consideration'', a second meeting is held. For each application reviewed, PTAC makes one of the following three possible recommendations to PHARMAC: (1) list the drug, (2) defer a decision until additional information can be supplied, or (3) decline to list the drug. If it selects the first option, PTAC also comments upon the priority that the drug should be given for listing. Regardless of the recommendation, PTAC provides a written report of the evidence/rationale used to support it. Using the Decision Criteria as its guide, PHARMAC may then choose to accept or reject the recommendation.		Upon receiving a referral from the DH and NAW, NICE first identifies relevant manufacturers, professional bodies, and patient groups who should be consulted during the review process, in addition to the DH, NAW, the Health Technology Board for Scotland (now HS Quality Improvement Scotland), and two health authorities. The scope and parameters of the appraisal, including questions that need to be asked about drug, are then established. To accomplish this, NICE's information specialists conduct a search of literature relating to the drug and prepare a draft scope for review by the consultees. The scope outlines the patient population and relevant subgroups, interventions requiring examination, necessary comparisons, and relevant outcomes for determining the drug's effectiveness. Once the consultees' comments have been submitted (within 10 working days), a final scope is produced. They are then asked to nominate experts to attend the first meeting of the Appraisal Committee. With the scope defined (which takes approximately 8 weeks), NICE commissions, through the NHS Co-ordinating Centre for Health Technology Assessment, an assessment group, which is an independent academic centre, to critically review the clinical and cost-effectiveness of the drug and provide an assessment report. All consultees may submit information to the assessment group for consideration. In addition, they are invited to a meeting with NICE executives and representatives from the assessment group to discuss technical aspects of the appraisal. When the assessment report is complete, copies are circulated to consultees for comment (within 10 working days). These comments, along with the assessment report, full submissions from professional and patient body consultees, and executive summaries of submissions from manufacturers comprise the evaluation report which is sent to the Appraisal Committee for review. The Appraisal Committee subsequently convenes to review this report and consider additional information provided by patient and clinical experts invited to attend its meeting. Once the Appraisal Committee has formulated its interim views, an appraisal consultation document is produced and distributed (within 7 working days of the meeting) to consultees and experts who attended the Appraisal Committee meeting. They then have 4 weeks in which to submit their comments on whether or not the document accurately reflects the evidence. During this ''consultation period'', the document is also posted on NICE's web site, allowing non-consultees the opportunity to submit their views for consideration by the Appraisal Committee. At the end of the consultation period, the Appraisal Committee meets again to review the evidence in light of any comments received. The final appraisal determination (FAD) containing the Appraisal Committee's final recommendations is then prepared (within 7 working days of the meeting) and submitted to NICE who, in turn, reviews it to ensure that the drug has been evaluated in accordance with the terms of reference outlined by the DH and NAW and the scope defined by NICE. At this point, the FAD is also posted on NICE's web site and sent to consultees. If deemed acceptable by all parties, and after all appeals, it becomes the basis of NICE's guidance on the use of the drug. Lastly, NICE sets a date on which the Guidance Executive of NICE (responsible for guideline development) will consider any new relevant evidence and produce an updated report. This date is referred to as the ''review date''.		In principle, drugs are considered for inclusion in the positive list at the manufacturer's request. However, the OFSP has the right to include or maintain a drug in the positive list against the manufacturer's will, when the drug is particularly important. In this case, the OFSP sets the reimbursement price unilaterally (OAMaL art. 70). A new product needs market authorization by the SATP and a positive reimbursement decision by the FOPH to be listed in the positive drug list (SL). After the marketing authorization has been granted by the SATP within 300 days, the pharmaceutical company submits a reimbursement application to the FOPH. The FOPH mandates the FDC to evaluate and classify a new drug in one of five categories: Therapeutic breakthrough, Therapeutic progress, Saving compared to other drugs, No therapeutic progress and no savings, and Not appropriate for the social health insurance.
Formal appeals mechanism	None stated.		Consultees may make an appeal against the FAD to NICE's Appeal Panel within 15 working days of the date at which it was issued. Grounds for an appeal must be clearly identified and pertain to: NICE exceeding its powers or not following published procedures or the FAD stating unreasonable recommendations, given the evidence submitted. Appointed by NICE's Board, the Appeal Panel comprises 5 members (including 1 non-executive director of NICE, 1 NHS representative, 1 individual with appropriate clinical expertise, and 1 member of a relevant patient or carer organization), none of whom have had any prior involvement in the appraisal. When the date for an appeal hearing has been set, the appellant is notified. All appeals are considered in private, with only findings becoming public. The appellant is informed of the outcome within 3 weeks of the hearing. If the appeal is upheld, the FAD and comments from the Appeal Panel are generally sent to the Appraisal Committee for reconsideration. Once any necessary amendments to the FAD are made, NICE revises it guidance to reflect them.		In case of a projected negative reimbursement decision the FOPH informs the applicant about the designated negative decision. The applicant may then apply for reevaluation before the official reimbursement decision has been issued by the FOPH. Arguments for reevaluation could be e.g. price adjustments or additional data. A second reconsideration application is possible with new evidence. Decisions of the OFSP pertaining to drug inclusion in the benefit basket can be contested via an internal appeal procedure.
Health Care Financing	Universal, public health care is available to all residents; private health insurance is also available for purchase, although it excludes coverage for unsubsidized pharmaceuticals. Access to public health care services and products occurs through a patient's primary health care provider or General Practitioner. New Zealand's stringent cost containment policies appear to be undermining the country's ability to develop a viable local pharmaceutical and biotechnology economy.		Public health care is available to all residents through the government-managed National Health Service (NHS). The NHS is funded primarily through general taxation, but also derives funds from national insurance contributions and patient co-payments. Private insurance schemes are available, and usually provide supplementary coverage.		Health Insurance is mandatory for all citizens in Switzerland. The legal basis is a federal law on sickness insurance (Krankenversicherungsgesetz, KVG). Management, delivery and financing of health services occur locally at the canton level. Each canton operates differently in response to the population's needs and size and within the given frame of the KVG. Financing of the system occurs through mandatory private insurance (65% of all funds) as well as government contributions, general taxation collected locally, and patient co-payments.

Pan-Canadian Pricing Alliance

Resource Requirements Template – CURRENT STATE:

The objective is to provide a best estimate of the resources required to:

(A) LEAD and/or

(B) PARTICIPATE in pan-Canadian files ONLY (see below).

Note: In some jurisdictions, clinical, business and support functions may not be differentiated and may be performed by the same staff/team. At this time, staff across jurisdictions are required to attend bi-weekly and ad hoc meetings as required.

JURISDICTION: _____

A. LEAD ROLE

of Products as LEAD: _____

ACTIVITY	CLINICAL	BUSINESS	SUPPORT
Monitoring & Tracking Formulary Working Group			
Clinical Review, Assessment & Establishing Criteria			
Budget Impact Analysis			
Value & Options Analysis			
Negotiation			
Letter of Intent			
Product Listing Agreement			
Formulary Listing (Special Authority, Forms & Training)			
Drug Education/Information			
Communications			
Contract Mgmt./Rebate Tracking/Invoicing/Renewals			
Ad Hoc/Sub-Group Meetings			
TOTAL FTE's			
TOTAL FTE's – BY TYPE (if available)			
Technical Skills & Team Composition			

B. PARTICIPANT ROLE

of Products as PARTICIPANT: _____

ACTIVITY	CLINICAL	BUSINESS	SUPPORT
Monitoring & Tracking Formulary Working Group			
Clinical Review, Assessment & Establishing Criteria			
Budget Impact Analysis			
Value & Options Analysis			
Product Listing Agreement			
Formulary Listing (Special Authority, Forms & Training)			
Drug Education/Information			
Communications			
Contract Mgmt./Rebate Tracking/Invoicing/Renewals			
Ad Hoc/Sub-Group Meetings			
TOTAL FTE's			
TOTAL FTE's – BY TYPE (if available)			
Technical Skills & Team Composition			

C. CURRENT PROCESS

Please Give a Brief Overview of Your Process from Beginning of Negotiation to Listing.	

APPENDIX 5

Interview Guide for Pan Canadian Drugs Negotiation Interviews

Introduction to project

The Pan-Canadian Pricing Alliance (PCPA) was announced by Premiers in August 2010, at a meeting of the Council of the Federation (COF). The approach capitalizes on the combined purchasing power of public drug plans across multiple jurisdictions, to improve the consistency of drug listing decisions across the country, to ensure benefits are cost effective and to increase access to drug treatment options.

In July 2012, the Council of the Federation directed Health Ministers to identify options to obtain better value for generic drugs. This follows on the work completed for brand name drugs and looks for opportunities to better value for money. With these announcements, participating provinces and territories (P/Ts) have continued to discuss the development of a formal process to support this pan-Canadian approach for both brand and generic drug reimbursement through the public drug plans ("initiatives").

Since P/Ts do not directly purchase drug products under the public drug plans, the focus has been on developing a common approach to drug product listing negotiations. The initial work has broadened to include identifying immediate and long-term approaches and opportunities to obtain better value for money for generic drugs. It should be noted, this initiative is not intended to bypass existing evidence-based drug reviews or the development of new listing approaches.

Ontario and Nova Scotia are the lead provinces for the PCPA for brand name drugs. Alberta and Saskatchewan are the leads for the generic initiative. Individual product listing agreement negotiations have been led by multiple jurisdictions including Ontario, British Columbia, Nova Scotia, New Brunswick, Saskatchewan and Alberta on behalf of participating jurisdictions. For this effort to succeed in the longer term, it is of vital importance that a formal governance structure is developed and consideration is given to the use of dedicated resources to guide these initiatives forward.

Project objectives

Our goal in interviewing you is to understand the current process followed by your jurisdiction and an assessment of the feasibility of establishing a separate new entity to manage the process.

The objectives of this PCPA project are the following:

Opportunities for better value for money for brand name and generic drugs
→ Increase the consistency of P/T drug funding recommendations and decisions

→ Increase the consistency of pharmaceutical pricing
→ Increase transparency of drug funding decision-making
→ Strengthen existing reimbursement review processes
→ Achieve savings through a managed approach to drug funding for generic and brand name drug products
→ P/Ts able to enter into funding arrangements with manufacturers to obtain better value

Under the direction of the Ministry and the other partnering P/Ts, IBM has been asked to recommend options for the development of a permanent model(s) that will facilitate negotiations for brand products and approaches to achieving better value for money for generic drugs. The options must consider feasibility of implementation including joint versus separate governance and administration of the two initiatives. This will require a detailed analysis of the current process, regulatory barriers within each jurisdiction, operational considerations and resource requirements. This interview will provide an important input for achieving the above objective.

Process we will be following with stakeholder interviews

IBM will be conducting interviews with a number of stakeholders including Provincial Ministries, Cancer Agencies, Industry stakeholders, Regulatory agencies and Patient groups. This interview guide provides you with a list of topics and questions that we will be reviewing with you. We have divided the questions into a) introductory questions which will allow us to gain an understanding of your jurisdiction and commonalities and differences across jurisdictions. b) PCPA experience questions c) Process questions d) Governance questions

The output of all the interviews will be systematically analyzed in order to understand the process conducted in various jurisdictions, commonalities and differences among them, and to recommend options for the development of a permanent model(s) that will facilitate negotiations for brand products and approaches to achieving better value for money for drugs. We will remain in touch regarding next steps as we make progress in this project.

Primary Interview Questions

A. Introductory questions

1) Can you describe the process your province follows after a final recommendation regarding a new drug from one of the national review bodies (i.e. pCODR or CDR)?

2) Are there ways to improve the alignment between pCODR/CDR and the PCPA?

3) Can you elaborate on the various components of current PLAs such as:

   - Standard length of the agreement (1 year, 3 year, indefinite), right of renewal?
   - how often rebates are reconciled (quarterly, annually),
   - Other standard terms they might include which differ or are not currently included

4) With the pan-Canadian process in place, do you think your jurisdiction will need the ability to:

   A) Negotiate product listing agreements locally (e.g. for products that have been reviewed separately for your province/territory (i.e., not CDR or pCODR eligible); or

B) Manage recommendations outside of a pan-Canadian framework?

C) Negotiate additional provisions (risk-sharing caps, DUR framework, coverage of wholesale mark-up charges, etc.) for agreements completed within the pan-Canadian framework?

5) How do you currently manage price increases for brand and for generic? Your thoughts on managing this differently with PCPA?

6) What are some of the key elements considered in the development of product listing agreements (it's not just price, what else is the negotiating factor or lever for parties involved - supply; patent timeline; certainty regarding clinical and cost effectiveness, budget impact, patient need (therapeutic gap), external/political pressures?)

7) Are there processes in your jurisdiction that do not align well with pan-Canadian negotiations (e.g. secondary review processes, approval processes, etc?)

B. Pan-Canadian Purchasing Alliance (PCPA) experience questions

8) Has your province led a negotiation through the PCPA?

9) What has been the "best" negotiation experience & why; What has been the most difficult/challenging & why – looking for "case study examples"

10) What has your experience been so far with the PCPA recognizing the process has evolved over time? What are the positive aspects?

11) What aspects have been frustrating and could use improvement. What are your suggestions for improvements?

12) Do you agree with PCPA's goals of increasing access, improving consistency, capitalizing on buying power, achieving consistent pricing and reducing duplication? Are these goals commonly shared by the various provinces or are there differences in opinion; if so, what are these differences? In your opinion to what extent has PCPA achieved these goals?

C. Process questions

13) Do you have a legislative or regulatory framework for your current drug negotiations process (brand and generic)? Can you give some detail about the framework? Do you have any general procurement rules across government that also applies to drugs?

14) Resource differences amongst the provinces suggests that PCPA could provide relief for personnel as well as processes and thus generate efficiency for negotiating drugs that fall under PCPA. Do you agree with this statement and if so, what areas are most important to you? What constraints does your province currently have with PCPA and more broadly?

    - What are your current resource requirements through PCPA (e.g. how many FTEs are your currently committing or average time commitment)
    - Can you comment on the outputs of the work involving PCPA? E.g. Have there have been more listings, have the listings been approved, has there been better pricing)

15) There has been some criticism from external stakeholders that the focus of pan-Canadian negotiations has been price. Are there other elements your jurisdiction would consider in a product listing agreement (e.g. research funding, utilization caps, outcomes-based agreements, etc.)?

16) Is your jurisdiction satisfied with the overall quality, clarity and "actionability" of the final recommendations and supporting analysis produced by pCODR/CDR? What improvements, if any, would you suggest?

17) Should there be a formal appeal process for drugs that the PCPA has decided not to negotiate? What is your opinion on the current status of accepting proposals for these drugs?

18) What metrics should be used to monitor and measure success of PCPA? Examples of metrics: Decision timelines, resource efficiency, cost savings – others?

19) Experience to date suggests that negotiations can vary drastically in the amount of time it takes to reach a conclusion, as well as the time taken to list a product within each jurisdiction. How long do you think a PCPA submission should realistically take for an

answer? Can this be improved and if so what are your recommendations? Do you think there should be suggested benchmarks within the PCPA process for both parties (government and industry)? What have been the reasons for the variations in your experience? Is there anything within the process than can be modified to assist your jurisdiction with timelines throughout the negotiation and approval process?

D. Governance questions

20) Does your jurisdictions current legislative/regulatory framework allow for the transfer of the overall responsibility of PCPA to a specific organization? Do you think there is a political willingness to do so? Are they willing to transfer negotiations process responsibility? Pricing responsibility? Contract offering/procurement responsibility? Final decision making? If delegations could be made, how much input into the process would your jurisdiction want to have?

21) Is there a natural existing national organization that PCPA could fall under or is a new organizational entity with a Pan Canadian mandate necessary? If so, what are some of the features that such an entity should have?

22) Is the concept of delegating authority to a single entity or jurisdiction for the sole purpose of negotiating funding agreements realistic, has it worked so far?

23) Do you think one governance structure could deal with negotiations for both brand and generic products?

24) As mentioned previously, there has been some criticism from external stakeholders that the focus of pan-Canadian negotiations has been price. Would you recommend a different name for the Pan-Canadian Pricing Alliance?

Secondary Interview Questions (pending time)

A. Introductory questions

1) In what areas do you think your province differs in policy/process in regards to drug listings?

2) How does your jurisdiction currently define “price” and determine “rebate” (percentage of public list price, confidential rebated price, and fixed net price/rebate) in existing PLAs?

3) If generic drug prices are regulated, how is "price" defined, what specific "pricing elements" are regulated and how does your jurisdiction manage "exceptions" to pricing regulations?

4) Have there been any recent changes or are you expecting any changes to the approach in drug pricing, negotiations, supply requirements in the jurisdictions; for a) brand name drugs and b) generic drugs why? For example, Pharmaceutical Price Regulation Scheme (PPRS) in the UK will be replaced by a value-based pricing mechanism next year.-

5) How do you currently evaluate existing/expiring PLAs to determine if actual budget impact is within an allowable range compared to the original BIA projections or if contract terms need to be revised?

6) How do you currently re-negotiate PLAs? What are your thoughts on re-negotiating PLAs that originated through the pan-Canadian process?

7) In some provinces PLA's include a donation for research, are you in favor of this or not? State why? Are there other models of 'contribution' that your jurisdiction might entertain?

B. Pan-Canadian Purchasing Alliance (PCPA) experience questions

8) What areas of PCPA could use flexibility, are there specific areas that must be consistent across the provinces?

9) Are there elements within the PCPA that are very difficult for your jurisdiction to implement which then take additional work after a LOI has been signed? If yes, do you have suggestions on how to resolve these?

C. Process questions

10) Prior to PCPA, how would you describe your negotiation process? What is your estimate on the percentage of brand products that were listed through a PLA (vs. no PLA)?

11) If the current structure were to continue is the concept of a Province taking a lead role for a certain drug for PCPA the right approach going forward or do you have a different suggestion- If this is the best approach then what is the best way of identifying the lead jurisdiction?

12) Do you think special criteria and a parallel process are needed for the negotiation process for drugs for rare diseases?

13) Any ways to improve sharing of information during negotiations?

14) Do you believe that the final pCODR/CDR recommendations receive the appropriate amount of weight when deciding if pan-Canadian negotiations will proceed? Is there a need to consider the recommendations of other bodies (international, provincial, etc?)

D. Governance questions

15) Is the concept of delegating authority to a single entity or jurisdiction for the sole purpose of negotiating funding agreements realistic, has it worked so far?

16) Do you think one governance structure could deal with negotiations for both brand and generic products?

E. Other stakeholder questions

17) How would you describe the level of participation and willingness of the pharmaceutical industry in previously held PCPA negotiations?

18) What areas can be improved if there negative experiences or positive-what were some of the reasons behind these? Could you provide examples

19) Can you suggest any best practices to share with industry from any positive experiences to date?

20) How do you think the public should be made aware of PCPA, its mandate and results? Are there specific measures of success that PCPA should subscribe to? How much information should be transparently available in the public domain?

21) Is there a risk of having a single supplier for generic drugs leading to over reliance on a particular supplier?

22) Are there any other comments that you would like to add that have not been covered above?

APPENDIX 6

Interview Guide for Pan Canadian Drugs Negotiation Interviews

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Our goal in interviewing you is to understand the pharmaceutical industry perspective on the PCPA process, the experience you have had with PCPA, and an assessment of the feasibility of establishing a separate new entity to manage the process.

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The output of all the interviews will be systematically analyzed in order to understand the process conducted in various jurisdictions, commonalities and differences among them, and to recommend options for the development of a permanent model(s) that will facilitate negotiations for brand products and approaches to achieving better value for money for drugs. We will remain in touch regarding next steps as we make progress in this project.

Questions for Interview Guide to be asked for Industry stakeholders

Introductory and PCPA Experience

1) What has your experience been with PCPA?
2) What is the perceived value of PCPA given the number of provinces that participate in negotiations?
3) By negotiating a drug through PCPA have there been any benefits to your organization?
4) Has your business model been impacted through PCPA? If yes, how.
5) What are your thoughts on the perceived utility/quality/timeliness of the national review processes (pCODR, CDR)? How do these national review processes integrate with current pan-Canadian processes (PCPA)?

PCPA Process

6) What has been the "best" negotiation experience and why; What has been the most difficult/challenging & why – looking for "case study examples"
7) How would you streamline the current process of PCPA? Are there immediately visible areas that can be improved for efficiency?
8) What do you think is the best process for a drug to be considered through PCPA? Please give an example of this best practice
9) What aspects have appeared consistent and inconsistent during the process of a negotiation through PCPA?
10) Are there a specific group of drugs you think should go through PCPA? Any you think shouldn't go through PCPA.

11) What are your thoughts regarding a Province taking a lead role for a certain drug for PCPA? Is this the right approach going forward or do you have a different suggestion-what is the best way of identifying the lead jurisdiction?

12) What are your suggestions for consistent listing criteria for drugs that fall under PCPA? Value for money is an important concept in today's fiscally tight health care world, what value for money criteria do you think PCPA need to include?

13) Do you think special criteria and a parallel process is needed for very expensive pharmaceuticals/biologics that are applicable to a small population?

14) Should there be a formal appeal process for drugs that the PCPA has decided not to negotiate? What are your specific thoughts on what an appeal process should entail?

15) Do you think special criteria and a parallel process are needed for the negotiation process for drugs for rare diseases?

PCPA Governance

16) Do you agree with PCPA's goals of:

- increasing access
- improving consistency
- capitalizing on buying power,
- achieving consistent pricing
- reducing duplication?

In your opinion to what extent has PCPA achieved these goals?

17) What would you see as the biggest concerns to your organization or to the pharmaceutical industry as a whole in terms of the mandate of PCPA?

18) Are there specific metrics to assess goals/objectives of PCPA

19) Is there a natural existing national organization that PCPA could fall under or is a new organizational entity with a Pan Canadian mandate necessary, if so, what are some of the features that such an entity should have?

20) Is the concept of delegating authority to a single entity or jurisdiction for the sole purpose of negotiating funding agreements realistic, has it worked so far?

21) Can you provide your thoughts on best practices for industry in this new pan-Canadian environment

22) Can you provide us with your thoughts on how best to communicate the process/status and results/metrics of pan-Canadian process

23) What are your thoughts on transparency of the PCPA process moving forward

24) We would like to better understand more of the industry's concerns about confidentiality of negotiations

25) Can you provide us with your input on timelines for the process – if we implement standards for response times, we would expect industry to also commit to response times. What are your thoughts on this?