China issues Guidelines and 2009-2011 Implementation Plan on Deepening the Reform of the Healthcare System

On April 6, 2009, the Central Committee of the Communist Party of China ("CCCPC") and the State Council jointly endorsed and issued the Guidelines on Deepening the Reform of the Healthcare System ("Guidelines"), followed by the Implementation Plan on Focuses for Deepening the Reform of the Healthcare System 2009-2011 issued on April 7, 2009 ("Implementation Plan"). The Guidelines focus on directions, objectives and policy structure to reform the healthcare system in the long term, while the Implementation Plan details objectives in the coming three years.

Priorities of China’s health reforms include:
- Expansion of health insurance programs, especially rural healthcare cooperatives
- Building hospitals and clinics
- Reducing government expenditures for drug costs

This memorandum addresses some of the efforts to control drug costs through the national essential drug system.

National Essential Drug System – Program Changes

One of the major reforms in the healthcare system in 2009-2011 will be the establishment of the National Essential Drug System, which covers three primary areas:

1) Establishing the administrative system to adjust the National Essential Drug List.

   The National Essential Drug List will be renewed periodically. Ma Xiaowei, Vice Minister of Health, said in early April 2009 that the formulation of the National Essential Drug List is the first task to establish the National Essential Drug System, and it was intended to be issued in April3. As of early May, however, the List has not yet been published.

2) Establishing a bidding process for essential drugs.

   Both the producer and the supplier of essential drugs used by government affiliated medical institutions may be required to participate in public bidding held by institutions designated by the provincial-level government. Enterprises in various regions and in various ownerships shall be treated equal in the bidding. Purchase/pricing of essential drugs with small dosage, and certain designated production/suppliers will be structured through bidding.

   The central government will set guiding retail prices for essential drugs, while provincial-level governments may set unified prices of essential drugs in the corresponding regions within the price scope set by the central government. Government affiliated basic medical institutions shall sell drugs to patients at the purchase price without markup.

3) Establishing a system that encourages the use of essential drugs.

   All government affiliated retail drug stores and medical institutions shall have and sell national essential drugs for patients’ needs. Urban and rural basic medical institutions shall all use national essential drugs, while other medical institutions shall give priority to the use of essential drugs and follow the requirement on utilization percentage of essential drugs which will be set by the health administrations later. All the essential drugs will be covered by the basic medical insurance system, and may see higher reimbursement rates than non-essential drugs in the insurance system.
New drugs and patented drugs will be subject to an economic evaluation to help determine pricing. The economic evaluation is intended to provide an objective analysis of quality, curative effect, cost, safety, and other clinical and economic features. These evaluations will contribute not only to drug pricing, but also to the formulation of a drug reimbursement catalogue, formulation of national essential drug list, and prescription plans at medical institutions for patients. Further, in order to control costs, new generic drugs will be required to be sold at the current lowest market price.

The markup percentage in the drug distribution will also be strictly regulated. Drug pricing in China currently is under the primary supervision of the National Development and Reform Commission (NDRC) and the State Food and Drug Administration (SFDA).

**Hospital Purchase/Sale of Drugs**

Another major reform involves restrictions on public hospitals’ purchase and sale of drugs. More specifically, hospitals will no longer be able to markup the price on drugs in sales to patients. The percentage markups of drug prices will be gradually eliminated. To protect hospitals from significantly reduced revenues, patients’ payment to hospitals for medical services will be increased, and the government will also increase subsidies to public hospitals on infrastructure construction, purchase of capital equipment, public sanitary missions, etc.. Basic medical services of non-profit medical institutions shall follow the guiding price set by the government, and medical institutions are independent to price other medical services. The central government will work out the pricing policies and measures on medical services, and the provincial-level or the municipal-level pricing authorities will set the guiding prices jointly with the administration of health, human resources and social security.

**Observations and Implications:**

The Guidelines and the Implementation Plan are another step for the Chinese government to lower drug prices. Provincial-level governments will have the power to set drug prices of essential drugs in the corresponding jurisdictions through public bidding. Essential drugs will be sold in government affiliated basic medical institutions at the purchase price without markup, while in the future, both essential drugs and non-essential drugs will be sold without markup in more medical institutions including public hospitals. Official figures suggest that currently, about half the income of China's general hospitals may come from price markups of the drugs sold to maintain operations. The government will reinforce the financial support to those institutions to maintain their daily operations.

The unified procurement of essential drugs is intended to be fair to both domestic and foreign invested drug companies, as pursuant to the Implementation Plan, "enterprises in various regions and various ownerships are equal in taking part in the fair competition" in the bidding.

To promote the reform, the State Council has established the Steering Team on Deepening the Reform of the Healthcare System, which is under the leadership of Vice Premier Li Keqiang and composed of officials from 16 ministries of the State Council including the National Development and Reform Commission, the Ministry of Health, the Ministry of Finance, the Ministry of Human Resources and Social Security, etc. The Steering Team will be responsible for formulating pilot program policies and principles. More affiliated documents and regulations on operations are expected to emerge soon.

**Key Dates/Quick History in the Development of China’s Healthcare Reform**

- **1949 to 1978:** China forms healthcare system with free medical treatment and services under labor insurance and cooperatives.
- **April 1985:** Ministry of Health says national medical system should be reformed to provide better healthcare services for citizens.
- **Sept 1992:** State Council issues circular encouraging hospitals to be run like enterprises and hold responsibility for their own operations and profits.
- **1994:** State Council approves general healthcare system trial in urban areas in Zhenjiang, Jiangsu Province and Jiujiang, Jiangxi Province.
- **Dec 1998:** State Council holds National Conference of Medical Insurance Reform, announcing it will set up general healthcare system for urban areas set up by 1999.
- **Feb 2000:** First healthcare reform launched. With the medical market opened, medical organizations cover most expenses with profit made from prescriptions and treatment.
- **Jan 16, 2003:** State Council to trial new rural cooperative medical care system in number of provinces.
- **July 2005:** Report from Development Research Center of State Council and World Health Organization states current healthcare reform is basically unsuccessful due to open market of healthcare sector, which marks beginning of new round of reform.
• **June 2006:** State Council sets up expert panel on new healthcare reform led by heads of National Development and Reform Commission (NDRC) and Ministry of Health; includes 16 ministries and departments.

• **Sept 2007:** NDRC announces new healthcare reform draft reports submitted to State Council.

• **Oct 14, 2008:** Long-awaited healthcare reform draft released by NDRC for public suggestions and comments at [http://shs.ndrc.gov.cn/yg/qwll/t20081014_240214.htm](http://shs.ndrc.gov.cn/yg/qwll/t20081014_240214.htm).

• **Jan 21, 2009:** Premier Wen Jiabao says State Council passes long-awaited healthcare reform plan that promises 850-billion yuan ($124 billion) budget by 2011 to provide universal healthcare to 1.3 billion population.

• **April 2009:** Guidelines and Implementation Plan of the medical reform released.

**About Reed Smith Richards Butler**

Reed Smith is a global relationship law firm with nearly 1,600 lawyers in 23 offices throughout the United States, Europe, Asia and the Middle East.

Founded in 1877, the firm represents leading international businesses, from Fortune 100 corporations to mid-market and emerging enterprises. Its lawyers provide litigation services in multi-jurisdictional matters and other high-stakes disputes; deliver regulatory counsel; and execute the full range of strategic domestic and cross-border transactions.

Reed Smith is a preeminent advisor to industries including financial services, life sciences, health care, advertising, technology, media, shipping, energy trade and commodities, real estate, manufacturing, and education. For more information, visit [reedsmith.com](http://reedsmith.com).

**US:** New York, Chicago, Los Angeles, Washington, San Francisco, Philadelphia, Pittsburgh, Oakland, Princeton, Northern Virginia, Wilmington, Silicon Valley, Century City, Richmond

**Europe:** London, Paris, Munich, Greece

**Middle East:** Abu Dhabi, Dubai

**Asia:** Hong Kong, Beijing

The information contained in this Client Alert is intended to be a general guide only and is not intended to provide legal advice. You should not rely upon the information contained in this Alert as if it were legal or other professional advice. This Client Alert was compiled up to and including May 2009.

A list of all Partners can be inspected at the website [www.reedsmith.com](http://www.reedsmith.com).

All rights reserved.