

Medical Device Reimbursement In China

Reimbursement has long been an issue of major concern to U.S. pharmaceutical manufacturers trying to sell their products in China. Recent developments have made the reimbursement an important issue for medical device manufacturers trying to sell in the Chinese market as well. Below is a broad outline of some of the factors that influenced the development of China's medical device reimbursement system, as well as a brief history of some of the major attempts to reduce the cost of medical devices in the Chinese market.

Introduction to China's Healthcare System

China's healthcare system has undergone a great deal of change since the era of "barefoot doctors" during the 1960's. While some of these changes are positive, such as the availability of world-class medical facilities in some parts of the country, the aggregate Chinese healthcare system is failing to meet the needs of a significant portion of its population. This is evidenced by the rising disparity between healthcare levels in the urban and rural areas in terms of the number of hospitals, funding and insurance available.

China's leaders have recently declared that China's healthcare system is in crisis, and Ministries responsible for healthcare have been tasked with making major reforms to the entire system. The focus of these reforms have been on narrowing the gap between services available to rural and urban citizens, as well as lowering the cost of care for all Chinese citizens. To understand how these changes are being carried out, and how they will affect U.S. manufacturers of medical devices, it is necessary to understand China's hospital and health insurance systems.

Hospital System

China has very few private hospitals, with the vast majority of hospitals administered by China's Ministry of Health (MOH) or other government entities at the provincial or local level. Hospitals are categorized as either Class I (township and county level), Class II (100 – 500 beds), or Class III (over 500 beds). The classification of hospitals plays a role in determining the types and amount of equipment a hospital can purchase. As of 2004, China had 977 Class III hospitals, 5,198 Class II hospitals, and 2,674 Class I hospitals, plus 8,995 others healthcare institutions.¹

One of the changes in China's healthcare system that has had the greatest impact on its citizens has been the gradual shift from strictly government controlled and financed system to a less centralized system in which hospitals received less central government funding in exchange for greater operating autonomy. During the 1950's and 60's, hospitals expenses and revenues were both controlled by the central government. During the 1970's and 80's, workers salaries at public hospitals were paid for by the central government and hospitals were allowed to use the fees they collected to pay for other

¹ Presentation by Misha Cao of the U.S. Department of Commerce given on May 18, 2006 at May 18, 2006 "China Risk, Reward & How to Win" Seminar in Washington, D.C.

costs. During the 1990's to the present, public hospitals were gradually given greater operating autonomy, and user fees supplanted government budgets as the main source of income.

Currently public hospitals are expected to generate revenue to cover 70 – 90 percent of their operating expenses.² In 2004 China's healthcare expenditure was 350 billion RMB, of which the government only contributed 50 billion RMB.³ Despite this low level of financial support from Central and Provincial-level government, Provincial-level Department of Health and Department of Price Administration officials still play an important role in determining fee schedules, including setting prices of treatments using medical devices provided at non-profit institutions.⁴

As government oversight was ceded from MOH to various ministries and state-owned enterprises, hospitals were given greater control over the purchasing of medical devices.⁵ This combination of reduced income from the central government and reduced oversight has led to a system in which the major sources of revenue for hospitals are user fees and drug mark-ups. As a result, China's healthcare system has been beset by over-prescription of medicines and unnecessary and expensive medical testing. There is anecdotal evidence that in some urban hospitals, the rate of C/T scans is 100 times higher than in comparable U.S. hospitals.⁶ These systematic flaws are prime causes of the current crisis in China's healthcare system.

Insurance System

Health insurance is an important aspect of most developed countries' healthcare systems. Since 1988, China has experimented with a number of health insurance schemes with very limited success. As a result, Chinese patients are required to pay the vast majority of treatment costs out of pocket. Chinese officials have recently acknowledged the problem of high out-of-pocket expenses, and are beginning to develop plans to strengthen the health insurance system for both urban and rural residents.

Mirroring China's chasm between economic development in urban and rural classes, China's health insurance system consists of two separate programs for urban and rural residents. The urban health insurance system is administered by the Ministry of Labor and Social Security, while the rural health insurance system is administered by the Ministry of Health. Both systems face significant obstacles to effectively covering their constituents.

² Medistat *World Medical Markets Analysis 2004*, (West Sussex, UK, Espicom Business Intelligence June 2004), p. 15.

³ Based on comments provided by the U.S. Department of Commerce's Trade Facilitation Office.

⁴ Misha Cao, "China Risk, Reward & How to Win" Seminar May 18, 2006

⁵ Unpublished report by U.S. Department of Commerce on a May 2006 Seminar at Beijing University Economic Research Center on Healthcare reform. May 13, 2006

⁶ May 13, 2006 U.S. Department of Commerce Report

Urban Health Insurance

In 1998, the State Council promulgated the “Decision on the Establishment of the Basic Medical Insurance System for Urban Staff and Workers”, which set out the basis for an urban health insurance system.⁷ This system utilizes both social pooling and individual accounts to address healthcare needs. Under this system, employees pay two percent of their wages into an account that is used mainly to cover outpatient procedures. Employers pay the equivalent of six percent of an employees’ wages to fund an insurance pool that is used to cover inpatient procedures.

Despite its well organized structure, the urban health insurance system remains woefully inadequate due to insufficient funding from the central government and the tendency of patients to over utilize in-patient care (because of the greater amount of funds available in the pooled system). In addition, there remains the aforementioned systematic bias towards excessive testing and prescriptions.

Urban Healthcare Reform

On November 13, 2005, MOH announced a plan to strengthen the urban health insurance system so that it would eventually cover 90 percent of the urban population and reimburse at least 50 percent of basic medical fees. How effective this program will be depends on whether China addresses some of the systemic problems such as excessive reliance on prescriptions and the over use of expensive testing to enhance hospital revenue.

Rural Health Insurance

China’s population is heavily concentrated in rural areas, with 70 percent of China’s 1.3 billion population living outside of the urban costal cities. However, only 25 percent of China’s rural population is covered by rural health insurance. As a result, virtually all rural primary health services are provided on a fee for service basis, with non-covered patients paying out of pocket for the vast majority of their treatment costs.⁸ In 2000, the MOH estimated that 87 percent of rural patients paid the full cost of their medical treatment out of pocket.⁹

The collapse of the medical collective system in rural China (best known for its “barefoot doctors”), coupled with heavy tax burdens and rampant local corruption, has cause considerable unrest amongst rural populations. In response, the Chinese government announced a plan in 2002 to guarantee the provision of primary healthcare to China’s rural population. The rural healthcare system is to be comprehensively overhauled and renamed the New Cooperative Medical Scheme (NCMS). The current target is for the plan to be fully operational by 2010.¹⁰

⁷ Misha Cao, “China Risk, Reward & How to Win” Seminar May 18, 2006

⁸ Misha Cao, “China Risk, Reward & How to Win” Seminar May 18, 2006

⁹ CHINA: Medical Device Market Intelligence Report

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¹⁰ See “Rural Health Insurance—Rising to the Challenge” World Bank Briefing Note 6, and CHINA: Medical Device Market Intelligence Report

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As part of this program, the central government began putting ten RMB each year into a medical account for each rural inhabitant, with the aim of building up an insurance fund. Individuals must also contribute ten RMB. Local governments will match these 10 RMB contributions for residents in low income areas. This system is eventually expected to be able to cover around 50% of medical costs.¹¹

Medical Device Reimbursement

Given the limited funding available from health insurance, China has attempted to limit medical device prices by introducing a number of reimbursement schemes that put downward pressure on the price that hospitals pay for devices (as well as for pharmaceuticals). Since 1999, the Chinese Government has required a formal tendering process for all imported products in order to strengthen the transparency of the purchase process and to reduce the price paid by the end user. However, the unintended results of these tendering schemes have been extra costs (tendering fees and bid bonds), lengthened purchase cycle times, and added bureaucracy.

Large Scale Equipment Tendering

China's reimbursement schemes treat capital equipment differently from other categories of devices such as implantables and disposables. On July 28, 2006, China's Ministry of Health announced a ban on individual hospitals purchasing large scale (over RMB 2 million (\$250,000) medical equipment. Instead, non-profit hospitals, and larger scale public hospitals (including SOE run institutions) would have to participate in collective purchasing of large scale medical equipment. The measures are designed to reduce the corruption associated with individual hospital administrators purchasing equipment. The measures will also give provincial-level health departments a larger role in purchasing decisions, which Chinese officials expect will lead to rationalization in the purchasing of expensive large scale medical equipment.¹²

Centralized Tendering Proposals

In an effort to hold down the cost of high-cost medical technologies, the National Development and Reform Commission (NDRC) has also worked with China's Ministry of Health on tendering schemes that address a wide arrange of medical equipment, especially high technology equipment such as implantables. The first proposal of this type was introduced by Shanghai Pricing Bureau officials in 2003.

Shanghai Pricing Plan

On April 1, 2003, the Shanghai government established a new pricing method and price ceiling for specific medical technologies, including many implantable devices. Under this proposal, distributors were required to submit an application for a retail price that included import prices directly to the Shanghai Medical Device Association. After collecting the pricing data, the Association would submit the data to the Shanghai Pricing Bureau, which would then use a formula for calculating the highest allowable price for

¹¹ "Rural Health Insurance—Rising to the Challenge" World Bank Briefing Note 6

¹² Pacific Bridge Medical (PBM) Asian Medical eNewsletter * Volume 6, Number 6 September 2006
http://www.pacificbridgemedical.com/newsletter/newsletter_v6n6.htm

the product. U.S. industry, with support from the U.S. government, was able to convince Shanghai officials that a more effective way of monitoring prices was to allow manufacturers to provide a recommended retail price. After a number of meetings with Shanghai officials, this proposal was adopted. In mid 2006, Shanghai officials introduced another pricing scheme based upon the original proposal that covered an even broader array of medical devices, claim that the original agreement was overtaken by the Centralized Tendering Program that was proposed by NDRC in early 2006 (see below). The American Chamber of Commerce and the U.S. Department of Commerce are presently working together to address concerns with the current pricing proposal.

Eight City Centralized Tendering

In 2005, China developed another tendering system in an effort to reduce medical device prices by an additional 30-50 percent. MOH introduced a pilot program affecting orthopedic and cardiac implants for the leading hospitals in eight geographic areas in China (Beijing, Shanghai, Tianjin, Chongqing, Guangdong, Hubei, Zhejiang, and Liaoning). This program was designed to favor companies operating without distributors (a process which was facilitated by China's accession to the WTO), whom Chinese officials believe contribute to high prices and corruption.

MOH proposed a "working committee" comprising pricing experts and doctors to make decisions on bids. An independent tendering company was responsible for organizing and initially assessing the bids, before a decision was rendered by the working committee. In exchange for the reduced costs, Ministry of Health officials were supposed to guarantee that hospitals would purchase set quantities of devices, and ensure payment within 30 days. U.S. industry's experience with this system was that prices set under this system became the de facto price ceilings for all hospitals, regardless of purchasing quantities, payment terms or other distribution costs. Ministry of Health discontinued this bidding system in early 2006, although some provincial governments are continuing to use a similar system for hospitals in their province.

NDRC Pricing Proposal

As part of China's effort to reform its healthcare system and reduce healthcare spending, the National Development and Reform Commission (NDRC) released a new proposal in January 2006 that would impose a limit on the total mark up on medical equipment from the factory price to the final sales price, as well as limit the mark up on medical equipment sold to consumers by medical institutions.

NDRC Healthcare Reform Taskforce

NDRC recently told Commerce officials that corruption in the distribution chain is the root cause of overly high prices of medical devices in China. Despite this, the NDRC proposal focuses on limiting the mark up to the end user, instead of specifically focusing on the distribution chain. These mark ups would be based on imported costs, with smaller markups for the more expensive products. NDRC's initial proposal also required manufacturers to provide sensitive CIF pricing information as well as pricing information from other countries to provincial level officials.

The U.S. Chamber of Commerce, AdvaMed, CAMDI (the Chinese medical device industry association), and the U.S. Department of Commerce have met repeatedly with NDRC officials in an effort to address some of the most egregious provisions of the draft regulation. Industry's has proposed NDRC utilize "recommended retail prices," which include the cost of post-sale technical support, instead of using import price, and on greater emphasis on problems in the distribution chain.¹³ NDRC is in the process of evaluating these proposals, and the U.S. government is closely monitoring NDRC's efforts.

National Development and Reform Commission, has also organized a taskforce, headed by the commission and comprising members from 11 ministries, to formulate a broad-based healthcare reform. The Taskforce is expected to announce a variety of healthcare reforms in early 2007.¹⁴ Media has reported that most Taskforce members favor Britain's National Health Service model, in which the government covers all public health expenses and basic medical insurance.¹⁵

¹³ Beijing American Chamber of Commerce (AmCham) letter to NDRC, April 1, 2006

¹⁴ "Holistic Medical Reforms", *China Daily*, September 21, 2006, p. 4

¹⁵ *South China Morning Post*, as reported by Factiva, October 11, 2006