

E-ALERT | Food & Drug / Anti-Corruption

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CHINESE GOVERNMENT MINISTRIES ISSUE OPINION ON IMPLEMENTING PHARMACEUTICAL REFORM

On December 13, 2013, nine governmental ministries in China jointly issued a policy document providing guidance to provincial and local governments on how to implement reform in the pharmaceutical and medical service industries.¹ The policy document was titled “Implementation Opinions on Carrying out a Special Campaign to Rectify Unethical Conduct in Medicine Procurement and Medical Services” (“Opinion”; a Covington translation can be found [here](#)). The issuance of the Opinion appears to be part of the government’s broader efforts at targeting corruption in the healthcare sector, including increased scrutiny and review of bribery, fraud, anti-competitive practices and pricing from administrative agencies such as the State Administration for Industry and Commerce, the National Development and Reform Commission (“NDRC”), the China Food and Drug Administration, and provincial and city governments.

The Opinion sets forth six targets for stricter regulation and enforcement: (1) pharmaceutical procurement; (2) supervision of medical institutions and staff and standardization of medical treatment; (3) government funding; (4) review and approval of drugs and medical devices; (5) drug prices; and (6) investigation and prosecution of unethical and illegal conduct.

While the Opinion is a good indicator of future policy in this area, particularly from these nine agencies, it does not create a specific timeline or plan for the drafting of regulations or specific rules. In addition, it does not change the rights or responsibilities of industry at this time. Rather, the Opinion reinforces the trend of increased government enforcement against bribery and corruption in the healthcare sector, as evidenced by the 2013 *Regulations on the Establishment of Commercial Bribery Records for the Purchase and Sale of Medicines*, and the 2013 *Nine Prohibitions for Strengthening Ethical Conduct in the Healthcare Industry*, both described [here](#). The Opinion may also serve as a guide for interpreting current regulations and understanding potential changes in enforcement priorities and practice, as well as a signal to closely monitor for proposed rules in this area.

PHARMACEUTICAL PROCUREMENT

In China, hospitals, clinics, and other medical institutions are predominantly state-run and obtain most of their drugs through a centralized bidding and procurement process at the provincial level. This complex and multi-step process presents many opportunities for corruption at each step, including selection for a provincial procurement list, procurement by a specific hospital, and prescriptions by an individual doctor, with problems exacerbated by an environment in which medical institutions are underfunded and doctors are relatively underpaid. In recognition of these problems,

¹ The nine ministries are the National Health and Family Planning Commission (the successor agency to the Ministry of Health), National Development & Reform Commission, Ministry of Industry and Information Technology, Ministry of Finance, Ministry of Human Resources and Social Security, Ministry of Commerce, State Administration of Taxation, State Administration of Industry and Commerce, and China Food & Drug Administration.

the Opinion stresses the general need to improve centralized procurement of pharmaceuticals (including using the national database of bid prices) to reduce the cost of pharmaceuticals. Provincial and local governments were also encouraged to increase their regulatory oversight over drug manufacturers and distributors, including a specific enforcement focus on the illegal use of invoices as evidence of commercial bribery. Provincial governments were also exhorted to establish and strengthen the blacklist system for healthcare companies blacklisted for bribery violations.

SUPERVISION OF MEDICAL INSTITUTIONS AND STAFF AND STANDARDIZATION OF MEDICAL TREATMENT

Another core area of concern is the standards for healthcare institutions. This area includes not only the standards for operations, but also the professional ethics and standards of care for treating patients. For example, China has previously identified as a key problem the perceived overprescribing of certain drugs, including antibiotics. In 2007, the Ministry of Health issued regulations standardizing prescription practices and mandating penalties for those who prescribe for personal gain or otherwise violate the regulations.² In 2012, the Ministry of Health issued regulations further circumscribing the “clinical use” of antibiotics in hospitals. The Opinion emphasizes the need to strictly implement the prescription regulations, monitor prescribing decisions, and publically criticize hospitals that over-prescribe. The Opinion also touches upon other enhancements in the area of medical treatment, including measures to improve medical ethics, such as implementing the *Code of Conduct for Professionals in Medical Institutions*³ and establishing a medical liability insurance system for settling medical disputes. For improving the supervision of medical institutions, the Opinion emphasizes the need for inspections of large hospitals and supervision of pricing established by medical institutions.

GOVERNMENT FUNDING

The Opinion emphasizes the need to more strictly regulate and reform funding of healthcare institutions and major state medical insurance programs. China instituted major reforms of its state medical insurance system in 2009, seeking to expand coverage to near universal levels by 2020. It currently has three major state plans, including one for state employees in urban areas, one of urban residents, and one for rural residents. The reimbursement levels under each of these plans varies by locality.

The Opinion seeks to reduce corruption, waste, and fraud with regard to government funding of both healthcare institutions and healthcare plans. The Opinion calls for provincial and local governments to increase supervision and inspection of funds to address fraud, abuse and waste with respect to the new model rural cooperative insurance program, the basic medical insurance program for urban residents, and funds for major public health service projects. The Opinion also cites the reform of government-provided medical insurance as a priority, including the investigation and punishment of insurance fraud.

² *Measures for the Administration of Prescriptions* (Ministry of Health, 2007), available at http://www.gov.cn/flfg/2007-03/13/content_549406.htm; *Administrative Measures for the Clinical Use of Antibiotics* (Ministry of Health, 2012), available at http://www.gov.cn/flfg/2012-05/08/content_2132174.htm.

³ As discussed in our previous client alert [here](#), the *Code of Conduct for Professionals in Medical Institutions* sets forth general standards and specific requirements for virtually every type of healthcare professional to follow, including not soliciting or accepting financial benefits from patients, not soliciting or accepting kickbacks or commissions, and not participating in illegal advertising and promotion or insurance fraud.

REVIEW AND APPROVAL OF DRUGS AND MEDICAL DEVICES

The Opinion calls for more attention to the safe manufacture of drugs and medical devices. In particular, the Opinion notes the need to promote the use of the *Good Manufacturing Practices for Drugs* and the *Good Manufacturing Practices for Medical Devices*, to formulate or revise standards for medical devices, and to increase supervision and inspection of high-risk medical device manufacturers (including manufacturers of sterile and implantable medical devices). It also calls for increased attention to post-market surveillance, such as improving the adverse event reporting system for drugs and medical devices, and strengthening the regulation of drug clinical trials, essential drugs, and drug excipients.

OVERSIGHT OVER DRUG PRICES

The government, through the NDRC and its local counterparts, sets or guides drug prices in China. Under China's Price Law, for example, the NDRC can set the Maximum Retail Price ("MRP") for drugs and vaccines covered by the National Reimbursement Drug List. Under China's Anti-Monopoly Law, the NDRC can enforce prohibitions against price discrimination and the charging of "unfairly high prices" by "dominant" companies. In response to public pressure, one of the key driving forces behind the pricing scheme currently is ensuring that drugs and medical services are affordable. The Opinion, therefore, recommends reforming drug pricing through various measures, including adjusting MRPs, setting uniform prices for certain essential drugs, and standardizing prices for medical services.

INVESTIGATION AND PROSECUTION OF UNETHICAL CONDUCT

The Opinion also continues with the general crackdown on corruption and fraud in the healthcare industry. It identifies numerous targets for increased investigation and prosecution: illegal pricing by health service providers, procurement violations, over-prescribing, arbitrary charges, receipt of "red envelopes" (i.e., bribes) by medical professionals, production and sale of fake drugs, false and illegal medical advertising, and commercial bribery in pharmaceutical sales. The Opinion recommends that the Public Security Bureau, Procuratorate (i.e., the public prosecutor), and the Administration for Industry and Commerce work together on commercial bribery investigations. These types of intra-agency efforts to investigate and punish the above behavior are becoming increasingly common.

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