

China Introduces New Health Care Sector Anti-Corruption Regulations

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As part of a concerted effort to tackle systemic commercial bribery in the country's health care sector, China's National Health and Family Planning Commission ("**Commission**") recently introduced separate new regulations aimed at hospitals and physicians, as well as the medical product companies that supply them.

On December 26, 2013, the Commission promulgated *Nine Prohibitions to Strengthen Ethical Conduct in the Healthcare Industry Circular [2013] No. 49* ("**Circular 49**"). Circular 49 imposes comprehensive anti-corruption compliance requirements on all hospitals and physicians in China, targeting the demand side of the bribery equation. This follows the *Regulations on Establishing of Commercial Bribery Records for Purchase and Sale of Medicines (Circular No. [2013] 50)* ("**Circular 50**") which were issued on December 25, 2013 and seeks to address the supply side with a blacklist of all pharmaceutical and medical device providers that engage in commercial bribery.

Circular 49: The "Nine Prohibitions"

Whereas most of China's regulations governing misconduct within the health care sector are vaguely worded and poorly enforced, Circular 49 is cut from different cloth. It aims to tighten control over hospitals and their employees through the following "nine prohibitions":

- Linking physician income to revenues generated from the sale of drugs or the provision of clinical services
- Paying or receiving rebates, commissions or other referral fees for drugs prescriptions or clinical services.
- Illegal price markups or surcharges that exceed China's official price standards for drugs or clinical services
- Accepting improper donations or subsidies from suppliers
- Participating in product promotional activities, illegal health care advertising or illegal disclosure of patient data
- Compiling statistical medical data for commercial purposes
- Procurement, sale or use of medical products outside of official channels
- Accepting kickbacks and commissions

- Accepting inducements from patients or their families

In recent years, China's health care system has become notorious for these practices but now anyone caught engaging in them will be subject to a range of disciplinary measures including reprimands, demotion, pay cuts, suspension or revocation of licenses. Violations that also constitute criminal conduct will subject violators to both prosecution and disciplinary action.

Circular 50: A New Blacklist System for Suppliers & Intermediaries

Once Circular 50 comes into force, on March 1, 2014, all drug and medical products suppliers and their personnel will be required to sign so-called 'Integrity Agreements' with each of the hospitals and other institutions with which they do business, detailing the names of their sales representatives and expressly promising not to engage in commercial bribery. Presumably, this prevents companies from later challenging the appropriateness of being blacklisted.

There is nothing new about drug and medical companies in China being blacklisted for bribery: many countries, including the U.S. exclude companies from participating in government health care programs if they are found guilty of certain misconduct. Under regulations introduced in 2007, Chinese provincial health bureaus were also required to maintain blacklists of companies suspected of bribing hospitals or their personnel but these regulations were poorly enforced and had little impact. However, under Circular 50, the net has been cast far wider and the consequences of being blacklisted are much more serious.

Circular 50 applies to all manufacturers, distributors and sales representatives of pharmaceuticals and other medical products, including medical devices, medical equipment and various medical supplies. Moreover, the range of circumstances that can result in blacklisting is more extensive than under the pre-existing regulations. They include:

- being convicted for serious or petty bribery
- being charged with or investigated for bribery regardless of whether or not authorities prosecute
- being subject to investigation and sanctions by CCP disciplinary authorities for bribery or bribery-related misconduct
- being subject to administrative penalties or sanction for bribery by a local finance bureau, the Administration for Industry and Commerce ("AIC") or China's State Food and Drug Administration ("SFDA")
- any other circumstances stipulated under laws and regulations

In other words, companies and/or their personnel can face blacklisting simply for being investigated for bribery, even if the conduct in question does not constitute a criminal offence.

Every provincial health bureau will be required to publish a blacklist on its website and submit details of blacklisted parties to the Commission which will publish them on its website, giving nationwide exposure to all wrongdoers.

Once a company or any of its personnel have been blacklisted, it will be barred from selling to any public hospital in the province concerned for a period of two years. Public hospitals account for the majority of hospitals in China. If a company is blacklisted two or more times in any five-year period, anywhere in China, it will be barred from selling to any public hospital and facility receiving State funding in China. Since state-funded facilities represent over 90% of China's health care system, being blacklisted could severely impact sales in the country.

The new blacklist system and penalties for non-criminal misconduct are both causes for concern with multinational manufacturers as some fear they may be used selectively to discriminate against them. Bribery investigations in China are very different from the U.S. and other foreign jurisdictions where formal charges can sometimes be avoided by voluntary settling with law enforcement agencies. There is no formal settlement process in China, which means that fewer companies will come forward if bribery is encountered through internal processes.

Context for these Regulations

These new regulations, introduced in the wake of sensational reports in the media last year about bribery by Chinese and multinational pharmaceutical companies, appear to be part of a systematic crackdown aimed at all players in China's health care industry, a crackdown which is only likely to intensify.

The first wave, between 2007 and early 2013, hinged largely on efforts to impose self-enforcement on China's health care industry and featured a largely voluntary blacklist system and whistle-blower incentives. This failed miserably, in part, because local officials seemed more concerned about loss of local tax revenue and employment opportunities than about stamping out corruption.

Next came heavier enforcement, in response to widespread allegations in the summer of 2013 against several multinational and Chinese pharmaceutical manufacturers. Since then, Chinese authorities have conducted a nationwide enforcement campaign, bringing a number of high-profile investigations against larger companies, which have resulted in arrests for bribery.

China's State media have been quick to point out that in virtually all of these cases, local personnel, circumventing their own company's internal controls and compliance policies, offered and paid huge bribes to physicians and/or culprits inside hospital procurement departments. However, in many instances, the bribery itself was brokered by agents or third-party intermediaries and the investigations were triggered by tip-offs from unidentified whistle-blowers.

These fact patterns help explain why these new regulations adopt a two-pronged strategy of criminalizing longstanding practices within China's health care system while adopting a blacklist system that will apply to all companies and individuals involved with supplying medical products. It is interesting to note that the role of whistle-blowing in enforcement is addressed in Circular 50 which requires all local health bureaus to designate personnel for receiving and investigating whistleblower complaints concerning bribery.

Expected Impact

It is likely that these regulations, will have a significant impact on the way that multinational companies sell drugs and other medical products in China.

Over the coming months and years, suppliers of medical products should expect much greater regulatory scrutiny over their operations in China and additional restrictions. Under pressure from the Commission, local and provincial health bureaus have already begun rolling out blacklists, implementing whistle-blower hotlines and tightening enforcement on the front lines.

On February 20, 2014, the Commission made headlines by announcing a decree which, from May 1, officially bans giving or accepting 'red envelopes' (ie: bribes) in connection with medical treatment at all large public hospitals. The decree will require hospitals to enforce 'integrity agreements' between patients and their attending physicians, forswearing bribery.

Of course, companies selling medical products in China need to ensure that their compliance policies and practices continue to comply with FCPA standards as well as with these new Chinese regulations. This may entail significant costs even for companies that recently reinforced their internal compliance programs for FCPA purposes.

To avoid facing a Chinese bribery investigation, companies need to be sure about not only the sufficiency of internal controls and policies but also the network of local business partners and intermediaries through which they do business throughout the country. Business relationships in China frequently extend more widely than expected and even if a company's direct trading partners are reputable, the third parties they deal with may not be. Companies must remain vigilant not only in vetting third parties but in ongoing oversight and updated due diligence.

Finally, time and effort will need to be invested in crafting appropriate strategies for dealing with investigations should they occur.

If you have any questions concerning this topic please contact Allan Goldner at agoldner@beneschlaw.com or 216.363.4623.