

China Anti-Bribery Rules Raise Questions For Life Sciences

Law360, New York (February 27, 2014, 6:40 PM ET) -- China's recent crackdown on bribery and corruption has been widely publicized, with enforcement particularly intense in the health care industry. In parallel with the heightened enforcement activity throughout China, the nation's health care regulator, the National Health and Family Planning Commission,[1] recently launched a three-year anti-commercial bribery campaign intended to specifically target 10 large cities and provinces, including Beijing, Shanghai, Tianjin, Zhejiang, Guangdong and Sichuan.

The first significant policy outgrowth of this anti-bribery campaign came in the final days of December 2013, when the commission issued two sets of rules to curb corruption and unethical conduct in the health care industry. On Dec. 25, 2013, the commission issued the Rules on the Establishment of Commercial Bribery Records for the Purchase and Distribution of Medicine[2] ("new blacklist"), which provides for the implementation of a blacklist of individuals and companies in the health care industry that have been subject to bribery-related investigations, penalties or convictions. A day later, the commission released the Nine Prohibitions to Strengthen Ethical Conduct in the Healthcare Industry,[3] which outline rules of conduct for industry participants.

The new blacklist and the nine prohibitions do not explicitly change pre-existing Chinese commercial bribery laws, but they reflect the commission's increased efforts to stamp out corruption in the health care industry and raise many important questions about the implications of these new rules on pharmaceutical and medical device manufacturers doing business in China.

Nine Prohibitions

The nine prohibitions are primarily directed to health care institutions and professionals, not pharmaceutical or medical device manufacturers, which is consistent with the commission's mandate to regulate the health care services sector. And, while the nine prohibitions appear notably broad at first glance, a somewhat narrower interpretation emerges upon a close examination in context of the overall Chinese policy framework.

The nine prohibitions primarily provide:

1. Incentives and Rewards

Health care institutions are prohibited from setting prescription targets for their departments and professionals. It is also prohibited to base health care professionals' compensation on revenues from medical examinations or sale of pharmaceutical products.

2. Commissions for Medical Services

Health care institutions may not provide commissions for prescriptions and providing medical services. Health care professionals are prohibited from charging commissions for referrals for medical examinations and treatments, and purchasing medical products.

3. Medical Costs and Expenses

Health care institutions may not charge for medical expenses outside of those set forth under nation pricing regulations.

4. Donations and Sponsorships

Health care institutions are required to accept donations and sponsorships in the name of the institution and donations must be handled by the institution's finance department. Donations and sponsorships may not be conditioned on terms that disrupt fair competition or be distributed as employee benefits. Health care institutions and professionals are prohibited from accepting sponsored international trips and disguised trips.

5. Promotions and Advertisements

Health care institutions and professionals are prohibited from releasing medical advertisements and participating in promotional activities for pharmaceutical, food and health care products. Illegal disclosure of personal and medical information of patients and recipients of medical services is also prohibited.

6. Prescription and Usage Information

Health care professionals are prohibited from collecting prescription and usage information for pharmaceutical and medical products for commercial purposes.

7. Purchase, Sale and Use for Private Purpose

Health care professionals are prohibited from illegally purchasing, selling and using pharmaceutical, medical device and medical products in private.

8. Kickbacks and Rebates

Health care professionals are prohibited from soliciting improper benefits or accepting kickbacks and rebates of any form from manufacturers or distributors. Health care professionals are also prohibited from attending any entertainment activities at for-profit entertainment venues organized or paid for by such pharmaceutical, medical device and medical product businesses.

9. Red Envelopes From Patients

Health care professionals are prohibited from soliciting and accepting cash, securities and expensive gifts from patients.

Given the broad and ambiguous language of several of the nine prohibitions, particularly in the English

translation, they have left industry participants with questions about how to craft compliance programs to avoid running afoul of these new rules. First, Prohibition 5, which prohibits health care professionals' participation in certain promotional activities for manufacturers, does not define "promotional" and thus some in the industry have wondered whether academic or educational promotional initiatives, like speaker programs, could be prohibited.

An analysis of the Chinese language version reveals, however, that the specific term for "promotional" used in Prohibition 5, "tui xiao," more commonly refers to commercial advertising and promotion directed to consumers, and not academic and medical information communicated by life sciences companies.

Under this view, Prohibition 5 does not restrict health care professionals' engagement in an academic or educational campaign organized by a drug manufacturer as speakers or presenters. Prohibition 5 also potentially raises the question whether pharmaceutical manufacturers are precluded from paying retail pharmacies for promotional space and activities directed to consumers (e.g., display fees). However, because retail pharmacies are generally not under the purview of the commission, Prohibition 5 is unlikely to apply to promotional activities in retail pharmacies, though it certainly signals a heightened scrutiny to anything directed to consumers.

Similarly, the English version of Prohibition 4, which precludes health care professionals from accepting sponsorships for "international trips," has raised the question of whether pharmaceutical or medical device companies are prohibited from sponsoring doctor's attendance at international academic events. Such a view, however, does not reflect the nuanced meaning of the Chinese word "lv you" and "bian xiang lv you," which should be interpreted as "leisure trips" and "disguised leisure trips."

Moreover, interpreting Prohibition 4 to include academic conferences sponsored by life sciences companies is contrary to the important policy objective to improve the quality of health care in China via international exchange of information, as most recently stated in the commission's Notice Regarding the 2014 Health and Family Planning Key Action Items.[4] A more contextually appropriate interpretation is that the commission is reiterating the prohibition against leisure travel and vacations paid for by health care companies, including those disguised as trips for academic purposes.

Finally, Prohibition 8, which prohibits health care professionals from attending entertainment activities organized or paid for by health care companies, does not define "entertainment activities" or "for-profit entertainment venues," and has raised questions about whether any form of entertainment (e.g., dinner or music) during an otherwise educational event could run afoul of the prohibition.

The Chinese version of the prohibition specifically uses the term, "ying ye xing yu le chang suo" for "for-profit entertainment venues," which refers to activities held at places that predominantly provide entertainment services, such as karaoke bars and night clubs. This prohibition is unlikely to affect hospitality of a modest nature offered at primarily clinical or educational events.

Aside from uncertainties arising from the textual interpretation of the nine prohibitions, the enforcement of these rules raises additional questions. Because the commission's rules and regulations are carried out at the provincial-level health bureaus, and not at the national level, it is likely that interpretation and enforcement of the nine prohibitions will vary widely from province to province (not an uncommon phenomenon in different regulatory landscapes in China).

The commission has not yet issued guidance to the provincial authorities regarding enforcement of the

prohibitions, and it remains to be seen whether it will attempt to standardize practices across provinces. However, it is likely that the commission will use the nine prohibitions as a rubric to evaluate the provincial health bureaus' performance in the campaign against bribery.

Finally, while the commission and its provincial counterparts do not enforce its rules on life sciences companies, the nine prohibitions can potentially be used as a basis for administrative or criminal penalties imposed by the local Administrations of Industry and Commerce (the civil commercial bribery enforcement body), the China Food and Drug Administration or the police.

New Blacklist Rules

The new blacklist, which goes into effect on March 1, 2014, amends and replaces a prior blacklist promulgated by the commission in 2007 (then Ministry of Health).[5] The old blacklist required provincial-level health bureaus to blacklist companies and individuals in the health care industry who have been investigated, penalized or convicted of bribery-related misconduct. State-funded hospitals and health care institutions were prohibited from purchasing products from blacklisted companies and individuals in the same province for a period of two years. The new blacklist extends the framework of the old blacklist while also expanding on some several key provisions.

Under the new blacklist, if a company or individual involved in the business of manufacturing or selling pharmaceutical, medical device, or medical products gives financial or other benefits to any employee of a health care institution in the course of procuring its products, it will be blacklisted if the conduct involves:

- A criminal conviction for bribery (including where criminal punishment is exempted for minor bribery offenses);
- A nonprosecution decision by the People's Procuratorate for minor bribery offenses;
- Investigation and decision for bribery by the disciplinary body of the China Communist Party;
- Administrative penalties for bribery from relevant administrative authorities; or
- Other circumstances as set forth under laws, regulations and statutes.

The new blacklist continues the two-year procurement ban under the old blacklist while also expanding several regulatory provisions. First, the commission will publish on its website a national blacklist containing all entities/individuals listed on the provincial blacklists. Next, the new blacklist expressly permits state-funded hospitals and health care institutions to reduce the bidding scores of companies blacklisted in other provinces in public procurement tenders.

The new blacklist also provides for more stringent penalties — any company or individual blacklisted twice within a five-year span will be suspended from supplying state-funded hospitals and health care institutions nationwide for a two-year period.

Finally, the new blacklist requires health care institutions to sign ethical purchase contracts with pharmaceutical and medical device manufacturers and businesses (and their respective agents and representatives) when entering into procurement and purchase agreements. The ethical purchase contracts are required to list the companies' designated sales representatives, and the companies must undertake not to engage in commercial bribery and acknowledge that failure to do so will result in being blacklisted.

Like the nine prohibitions, the enforcement of the new blacklist remains uncertain in significant part because the old blacklist was inconsistently implemented across China's provinces. For example, some provincial health bureaus reportedly only blacklisted companies for criminal bribery convictions, ignoring the other stipulated criteria for bribery-related investigations and administrative penalties. There was also very little coordination among the local Administrations of Industry and Commerce, other law enforcement bodies and the local health bureaus.

As a result, information regarding commercial bribery enforcement actions and convictions were not effectively communicated to the local health bureaus that maintained the blacklists. Further, the blacklists were largely opaque or, at a minimum, not well publicized, as many provincial health bureaus do not make their blacklists available on their official websites.

The new blacklist suggests a more robust and cross-provincial implementation approach, though there is little guidance yet about how this broader approach will work in practice. Both the plans for a centralized, public blacklist and point deductions for procurement tenders from companies blacklisted in another province reflect the intention to improve cross-provincial enforcement. Meanwhile, the more severe nationwide procurement ban for repeat offenders suggests a tougher approach toward deterrence and punishment.

Questions remain regarding how each provincial health bureau will interpret the blacklisting criteria and whether the commission will issue further guidance to standardize the practice. Another question is whether companies will be able to limit the impact of being blacklisted through manipulating corporate group and affiliate structures.

To date, the commission has not issued any statements about how it plans to implement and enforce the new blacklist rules. However, given the current policy climate to root out corruption, individual provinces may act quickly to adopt the new blacklist and formulate their own implementation policies.

The first may be Sichuan's Provincial Health Department, which released on Feb. 19, 2014, the draft Sichuan Province Medical Purchase and Sales Industry Commercial Bribery Blacklist Implementing Rules for solicitation of comments. We will following closely to see how these and other implementing rules will ultimately be promulgated and enforced.

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[1] In Chinese: 中华人民共和国国家卫生和计划生育委员会. It is the body that succeeded the Ministry of Health (卫生部), or "MOH," in regulating the health care industry in China.

[2] Rules on the Establishment of Commercial Bribery Records for the Purchase and Distribution of Medicine (Circular No. [2013] 50); in Chinese:

《关于建立医药购销领域商业贿赂的不良记录的规定》。

[3] Nine Prohibitions to Strengthen Ethical Conduct in the Healthcare Industry (Circular No. [2013] 49); in Chinese: 《加强医疗卫生行风建设“九不准”的通知》。

[4] Released by the National Health and Family Planning Commission on January 27, 2013; in Chinese: 《卫计委关于印发2014年卫生计生工作要点的通知》。

[5] Notice Of The Ministry Of Health On Issuing The Provisions On The Establishment Of The Black List For Commercial Corruption In The Sales And Purchase Of Drugs (Circular No. [2007] 28); promulgated by the Ministry of Health on January 19, 2007; in Chinese:

《卫生部关于印发《关于建立医药购销领域商业贿赂不良记录的规定》的通知》。

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