

## E-ALERT | Anti-Corruption / Life Sciences

December 31, 2013

### CHINA ISSUES NEW RULES FOR BLACKLISTING HEALTHCARE COMPANIES ENGAGING IN COMMERCIAL BRIBERY ETHICS RULES FOR HEALTHCARE PROFESSIONALS ALSO UPDATED

On December 25, 2013, China's National Health and Family Planning Commission ("NHFP," the successor to the Ministry of Health) issued the *Regulations on the Establishment of Commercial Bribery Records for the Purchase and Sale of Medicines* ("2013 Blacklist Rules"; a Covington translation can be found [here](#)), which require details of companies blacklisted at a provincial level for commercial bribery violations to be published on a national website.<sup>1</sup> The rules, which reinforce and expand similar rules issued in 2007 and 2010, will take effect on March 1, 2014. The new blacklists pose significantly more commercial and reputational risks for companies operating in the healthcare sector.

In a separate but related development, the NHFP on December 26 promulgated *Nine Prohibitions for Strengthening Ethical Conduct in the Healthcare Industry* ("Nine Prohibitions"; a Covington translation can be found [here](#)), effective immediately, which reiterate and expand on earlier regulations prohibiting certain conduct by healthcare professionals ("HCPs") and healthcare institutions.

These two developments evidence a continuing emphasis by PRC authorities on cracking down on bribery and corruption in the healthcare sector from both the supply and demand sides.

#### Background on 2007 and 2010 Blacklist Rules

In 2007, the Ministry of Health ("MOH"), the predecessor to NHFP, issued the *Rules on Establishing a Blacklist System for the Purchase and Sale of Pharmaceutical Products* ("2007 Blacklist Rules"). Under the 2007 Blacklist Rules, hospitals in a province are prohibited for two years from purchasing drugs, medical equipment, or medical supplies from healthcare companies blacklisted in that province for bribery violations. The 2007 Blacklist Rules also require provincial health authorities to establish a blacklist system and publicize and update blacklists on their respective websites.

To further implement the 2007 Blacklist Rules, in 2010 MOH promulgated the *Notice on Further Crackdown on Commercial Bribery in Purchase and Sale of Pharmaceutical Products* ("2010 Notice"), which requires the blacklist system to be established in all provinces by the end of 2010. In addition to the two-year purchasing ban established in the 2007 Blacklist Rules, the 2010 Notice adds that blacklisted companies also will be banned for two years from bidding for drug procurement programs.

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<sup>1</sup> The term we translate as "blacklist" in Chinese is "不良记录," which literally means "bad record." We use "blacklist" throughout this e-alert for ease of reading.

## The 2013 Blacklist Rules

Under the 2013 Blacklist Rules, which build on their 2007 and 2010 predecessors, companies listed on the newly created national blacklist are subject to the following penalties:

- *Broader dissemination of company's name and violation.* Under the 2013 Blacklist Rules, the NHFPC will establish and publicize a national blacklist in parallel with the pre-existing provincial lists established in the 2007 and 2010 rules.<sup>2</sup> Provincial health administrations will submit entries on the provincial blacklists to the NHFPC within a month after they publicize their blacklists, and the NHFPC will then add the names of the companies or individuals to the blacklist on its website. Information to be included on the public list will include the company name, business addresses, legal representative/person in charge, person directly responsible for the violation, the violation, the penalty, and the start and end dates of the ban. Because provincial blacklists have to date been only sporadically maintained, the centralized blacklist may expose blacklisted companies or individuals to much greater reputational risks and draw scrutiny from national regulators.
- *Procurement-related penalties in other provinces.* In addition to being subject to an outright ban on procurement in the province in which a company or individual is blacklisted, companies and individuals blacklisted in one province will have “points deducted” from their procurement scores during the procurement process in other provinces. (The 2013 Blacklist Rules do not provide additional details on this sanction.)
- *Nationwide blacklist for repeat offenders.* Companies and individuals whose names appear on any provincial blacklist two or more times within five years will be blacklisted nationally for two years.

The 2013 Blacklist Rules further require drug manufacturers, distributors, and their agents to sign an “Honesty and Integrity Purchase and Sale Compact” (“Integrity Compact”) with hospitals when they enter into a procurement contract. The Integrity Compact will include the name of the sales representatives designated by the company, and anti-corruption provisions that clearly describe the blacklisting penalties discussed above.

## Nine Prohibitions

One day after releasing the 2013 Blacklist Rules, NHFPC released the Nine Prohibitions, which outline prohibited conduct for HCPs and healthcare institutions. Many of the prohibitions largely mirror those found in previous regulations issued by NHFPC and its predecessor, MOH, including the *2012 Code of Conduct for Professionals in Medical Institutions* (see our e-alert [here](#)).

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<sup>2</sup> The 2007 Blacklist Rules and 2010 Notice applied to all healthcare institutions in a given province. The prohibition on purchase/procurement in the 2013 Blacklist Rules applies only to “public healthcare institutions or healthcare institutions that accept [public] financial funding” in a given province.

Most of the prohibitions relate to interactions between HCPs, healthcare institutions, and the public. Many of them, however, potentially implicate business practices by manufacturers or other companies in the healthcare sector. Of particular note for healthcare companies, the Nine Prohibitions includes a ban on accepting improper “donations and subsidies” from outside parties, and specifically includes a prohibition on “accepting donations or subsidies [in the form of] international tourism or disguised tourism.” The Nine Prohibitions also refine slightly an earlier ban on participating in “entertainment activities [held] in commercial entertainment venues” provided by companies in the healthcare industry.<sup>3</sup>

The Nine Prohibitions are summarized as follows:

- Healthcare institutions shall not link HCPs’ incomes to profits generated from medical checkups or the sale of drugs.
- Healthcare institutions shall not provide HCPs with rebates for their prescriptions; HCPs shall not solicit or accept rebates for introducing patients to other entities for medical checkups or treatment or recommending patients to purchase certain medical products.
- Healthcare institutions shall not illegally overcharge patients.
- Healthcare institutions shall not accept social donations and subsidies when doing so violates applicable law and regulations.
  - Donations to institutions must be handled by the finance department of the institution and must be pursuant to a written donation agreement and for a not-for-profit purpose.
  - Neither individual departments nor individual HCPs may accept donations or subsidies.
  - Healthcare institutions shall not accept donations or subsidies attached with conditions that may affect fair competition and shall not link donations and subsidies to the purchase of products or services.
  - Healthcare institutions and HCPs shall not accept international tours (or tourism-in-disguise) sponsored by healthcare companies.
- Healthcare institutions and their professionals shall not illegally release medical advertisements, or participate in promotional events of medical products, food, healthcare products or other commodities, or disclose the personal data and medical information of patients.
  - (No details are provided that define or explain “promotional events.”)
- HCPs shall not collate statistics on prescriptions for commercial purpose or provide benefits to medical sales personnel to collate statistics.
- HCPs shall not illegally procure, sell, or use drugs, medical equipment, medical supplies, etc. in private.
- HCPs shall not solicit or accept kickbacks, commissions in any form provided by healthcare companies, or engage in any entertainment activities held in commercial entertainment venues arranged, organized or paid for by healthcare companies.
- HCPs shall not solicit or accept financial benefits from patients, including “red envelopes.”

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<sup>3</sup> The 2012 Code of Conduct prohibited HCPs from participating in “commercial entertainment activities” without reference to the location of the entertainment.

A violation by an HCP may result in a range of disciplinary actions against the offending HCP, including disqualification for advancement opportunities in that year, suspension of the HCP's employment contract, revocation of the HCP's professional license, and criminal liability.

## Significance and Implications

These two developments evidence a continuing emphasis by PRC authorities on cracking down on bribery and corruption in the healthcare sector from both the supply and demand sides.

The national-level blacklist is a significant expansion of the blacklist program. While the provincial-level blacklists have been in place since 2007, implementation has been uneven and, in many provinces, absent. The new penalties for a commercial bribery violation in one province, which would result in being included on the national-level list, are significant, particularly the threat of disadvantages during bidding for government procurement in other provinces and the possibility of nationwide blacklist for repeat offenders. Companies will continue to be subject to monetary penalties for commercial bribery violations, but the threat of blacklisting from sales to public-sector medical institutions in a province – or nationwide – presents a significantly larger commercial (and reputational) risk.

The Nine Prohibitions seek to address the “demand” side of bribery in the healthcare sector by outlining, with additional clarity, prohibited conduct by HCPs and healthcare institutions. While the prohibitions are directed on their face at HCPs and institutions, several of the provisions also directly implicate business practices by manufacturers in areas such as donations, sponsorships, and entertainment. These prohibitions may warrant healthcare companies to reevaluate policies and controls in these areas to mitigate risk for themselves and their customers.

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If you have any questions concerning the material discussed in this client alert, please contact the following China-focused members of our [Global Anti-Corruption Practice Group](#) or [China Life Sciences Practice](#):

<b>Eric Carlson</b>	86.10.5910.0503	<a href="mailto:ecarlson@cov.com">ecarlson@cov.com</a>
<b>Shaoyu Chen</b>	86.21.6036.2509	<a href="mailto:schen@cov.com">schen@cov.com</a>
<b>Weishi Li</b>	86.21.6036.2502	<a href="mailto:wli@cov.com">wli@cov.com</a>
<b>Hui Xu</b>	86.21.6036.2508	<a href="mailto:hxu@cov.com">hxu@cov.com</a>
<b>Chaohui Liang</b>	86.10.5910.0313	<a href="mailto:cliang@cov.com">cliang@cov.com</a>

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