



November 2015

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China Releases New Regulations on Donations to Healthcare Entities: Implications for Multinational Healthcare Companies

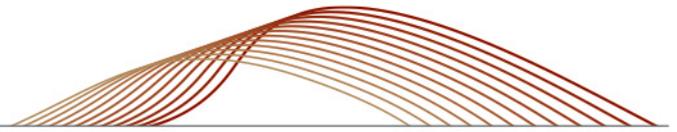
By [Ananda Martin](#), [Haiyan Tang](#), [Todd Zhou](#) & Baker Chen

In recent years, fighting corruption in the healthcare sector both domestically and abroad has been a major focus of U.S. regulators.¹ In China, regulators have also sought to stamp out graft in the medical industry by aggressively enforcing domestic anti-corruption laws against both Chinese and multinational companies. In line with these efforts, the Chinese government has implemented a number of legislative reforms designed to strengthen the regulatory framework. First, China's National Health and Family Planning Commission ("NHFPC") issued *Circular 49*, effective December 26, 2013, which addressed the demand side of improper payments in the healthcare industry by prohibiting Chinese healthcare professionals ("HCPs") and medical institutions from engaging in certain kinds of commercial activity.² Next, the NHFPC issued *Circular 50*, effective March 1, 2014, which strengthened blacklisting rules for healthcare companies that provide bribes to state healthcare institutions and medical personnel. Most recently, on October 20, 2015, the NHFPC substantially overhauled rules governing donations to healthcare organizations by issuing the *Administrative Regulations on Acceptance of Public Welfare Donations by Healthcare and Family Planning Organizations (Trial Implementation)* (the "2015 Donation Regulations"), superseding the *Interim Administrative Regulations on Acceptance of Social Donations and Sponsorships by Healthcare Institutions* promulgated in 2007 (the "2007 Donation Regulations"). A link to the Chinese text can be found [here](#). The 2015 Donation Regulations clarify the requirements for donations and sponsorships to healthcare entities such as hospitals and medical associations. At the same time, they highlight Chinese regulators' continued focus on this sector amidst a nationwide campaign against the "tigers and the flies" of domestic corruption. Multinational healthcare companies operating in China should review the 2015 Donation Regulations carefully to ensure that their medical education and corporate social responsibility ("CSR") programs are compliant with the new rules.

The 2015 Donation Regulations

The 2015 Donation Regulations strengthen the administrative and oversight powers—and responsibilities—of recipients. Key provisions of the 2015 Donation Regulations include:

- **Centralized Donation Management:** The 2015 Donation Regulations emphasize that healthcare entities, as opposed to their departments or employees, must be the recipients and managers of donations. The new rules require healthcare entities to designate a "Donation Management Department" to exercise central management over gifts.

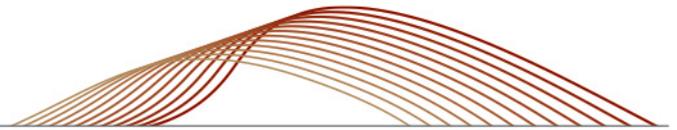


- **Clear Limitations on Acceptable Donations:** The 2015 Donation Regulations clarify which types of donations are prohibited. These include: (a) donations related to for-profit commercial activities, (b) donations suspected of constituting unfair competition and commercial bribery, (c) donations associated with procurement of goods or services by healthcare entities, and (d) donations giving rise to conflicts of interests under any applicable regulatory or law enforcement mandates.
- **Pre-evaluation Process:** The 2015 Donation Regulations revise the procedures that healthcare entities must follow before accepting donations. The new rules place responsibility for prior due diligence upon the Donation Management Department and permit healthcare entities to involve third parties and regulators in that process.
- **Donation Agreements:** The 2015 Donation Regulations clarify rules regarding donation agreements. Significantly, under the new rules, donors may not designate specific beneficiaries when supporting the training, academic, or healthcare activities of HCPs.
- **Cash Donations:** Consistent with the goal of promoting centralized control over donations, the 2015 Donation Regulations stipulate that, “in principle,” donations must be made via wire transfer and that such transfer be made directly to the bank account of the recipient entity (as opposed to individual HCPs).
- **Periodic Audits:** The new rules require healthcare entities to perform periodic audits of donated funds and to include information regarding the use of such funds in their annual financial reports to regulatory authorities.
- **Transparency:** The 2015 Donation Regulations increase the disclosure obligations of donation recipients both to donors and the general public and provide detailed guidance on the content, timing, and manner of those disclosures. The new rules also provide guidance on how to appropriately respond to public inquiries.³

Implications for Multinational Healthcare Companies

The 2015 Donation Regulations underline the Chinese government’s continued determination to combat the demand for improper payments in the healthcare sector. Given this heightened focus, multinational healthcare companies in China, which in recent years have come under regulatory review in increasing numbers, should consider the following measures:

1. **Donation and Sponsorship Agreements:** Healthcare companies should carefully review and amend, as necessary, their donation and sponsorship agreements with donees to ensure compliance with the new rules. In particular, while many healthcare companies’ medical education programs already prohibit donations to specific individuals, they should ensure that payment provisions are consistent with the 2015 Donation Regulations. Approvers should ensure that entities, not individuals, are the ultimate recipients of donated funds.
2. **Pre-evaluation Process:** Prior to the new rules, compliance-conscious healthcare companies regularly conducted due diligence on grant recipients. The new pre-evaluation requirement means that multinational corporations seeking to sponsor medical programs in China should themselves be prepared to be vetted. Donors should anticipate engaging with third-party agencies and regulators acting on behalf of healthcare entities, and adopt rigorous internal review and approval standards for their medical programs to ensure compliance with the new rules.



3. **Periodic Audit and Follow-up Review:** The new disclosure requirements may help corporate donors gain valuable insight into the way their funds are used, supplementing existing compliance procedures. While many multinational healthcare companies already require donees such as medical associations to provide verification of how donations are used, such information, particularly in large-scale, multi-year programs, is sparse and difficult to verify. Third party service providers retained by healthcare entities to organize medical studies or conferences provide additional layers of uncertainty. Healthcare companies are frequently placed in the difficult position of choosing between the transparency mandated by their compliance agenda and maintaining independence from marketing objectives. Companies seeking to strengthen oversight over medical education grants should leverage the financial reports and other required disclosures as a means of crosschecking internal data to ensure that funds are spent in accordance with donation agreements and accurately reflected in the company's books and records.
4. **Transparency:** Healthcare entities are typically required by corporate donors to maintain confidentiality regarding the details of charitable donations and sponsorships they receive. However, the new rules place certain public disclosure obligations on healthcare entities, exposing corporate CSR initiatives and budgets to greater regulatory scrutiny. It is therefore even more important that multinational healthcare companies ensure full compliance with the 2015 Donation Regulations, review their existing standard operating procedures governing charitable donations and education grants, and review their confidentiality agreements with donees to ensure that such agreements adequately protect corporate data while accommodating donees' enhanced disclosure obligations.

Action Items for Compliance Counsel

While the 2015 Donation Regulations shed welcome light on an important area of Chinese healthcare regulation, many key provisions remain open to interpretation. For example, although the 2015 Donation Regulations prohibit multinational corporations from directly entering into sponsorship agreements with individual HCPs, whether this prohibition would effectively ban sponsorship of an individual doctor's travel to attend an overseas conference under a contract with that doctor's hospital is unclear. Until the ink on the 2015 Donation Regulations dries and regulatory interpretation is clarified by actual enforcement, multinational healthcare companies should handle charitable donations with extra care.



If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

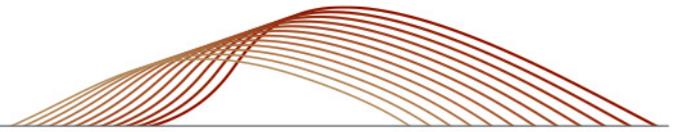
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- ¹ See, e.g., What Comes Next? Against the Backdrop of the Yates Memo, Novartis Announces a \$390M Healthcare Settlement, Paul Hastings Client Alert (November 2, 2015), available at [http://www.paulhastings.com/docs/default-source/PDFs/stay-current-what-comes-next-against-the-backdrop-of-the-yates-memo-novartis-announces-a-\\$390m-healthcare-settlement.pdf](http://www.paulhastings.com/docs/default-source/PDFs/stay-current-what-comes-next-against-the-backdrop-of-the-yates-memo-novartis-announces-a-$390m-healthcare-settlement.pdf); Your Joint Venture In Fact Can Be Your Problem: Bristol Meyers Squibb Pays \$14M to Resolve FCPA Allegations, Paul Hastings Client Alert (October 15, 2015), available at <http://www.paulhastings.com/docs/default-source/PDFs/stay-current-bms-client-alert.pdf>; and Here We Go Again—The U.S. Government Brings Home Another FCPA Case Against a Life Sciences Company, Paul Hastings Client Alert (November 12, 2014), available at <http://www.paulhastings.com/docs/default-source/PDFs/stay-current---here-we-go-again-the-u-s-government-brings-home-another-fcpa-case-against-a-life-sciences-company.pdf>.
 - ² See Legislative Reform of China's Healthcare Sector Targets Corruption: Implications for Multinational Companies, Paul Hastings Client Alert (August 28, 2014), available at https://www.paulhastings.com/docs/default-source/PDFs/china-matters_-legislative-reform-of-chinas-healthcare-sector.pdf?sfvrsn=0.
 - ³ The original Chinese wording is “zhìyí” (质疑), which can be translated as “to question,” but also carries the more confrontational connotation of “to call into question.” This suggests that members of the public could, in theory, challenge the validity of grant disclosures.

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