

China Adopts New Rules on Healthcare Donations

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Food & Drug / Anti-Corruption

On October 20, 2015, China's chief healthcare regulator, the National Health and Family Planning Commission (NHFPC), published a significant revision to its earlier rules on donations to healthcare entities.¹ This category of entities includes the nation's network of state-run hospitals and clinics where approximately 90% of citizens get their healthcare. The revised rule, "[Administrative Measures on Accepting Donations for Public Welfare by Healthcare Entities \(for Trial Implementation\)](#)" (the "New Donation Measures," see Covington's English translation [here](#)) replaced the *Interim Measures for the Administration of the Acceptance of Social Donations and Financial Aid by Healthcare and Health Institutions* ("2007 Measures"), which had not been revised since 2007. The New Donation Measures, which take effect immediately, technically apply only the receipt of donations by healthcare entities. In practice, however, the New Donation Measures establish detailed guidelines for entities and individuals who wish make charitable contributions to an expanded variety of entities, such as hospitals, societies, foundations, and other social welfare organizations (collectively "healthcare entities").

The New Donation Measures are significantly broader in scope and contain more restrictions than the 2007 Measures. *First*, the New Donation Measures apply to both foreign and domestic donors and include additional types of healthcare-related donees, such as public welfare societies, foundations, and other charitable organizations. *Second*, the New Donation Measures provide more details regarding the circumstances under which donations are both allowed and prohibited. *Third*, the Measures create a new institutional review mechanism prior to accepting a donation. *Fourth*, they provide more detailed and stringent restrictions on making and accepting donations, including among other items, requiring that donors donate via bank transfers and certify that the contributions are from legitimate sources. *Finally*, the New Donation Measures increase transparency by requiring healthcare entities to make information about donations publicly available and subject those arrangements to potential audits.

A provision-by-provision comparison of the 2007 Measures and the New Donation Measures is included below.

Expanded Scope of "Donations"

The New Donation Measures apply to "donations," that constitute social welfare support and aid in the form of cash and other property. They are from both foreign and domestic individuals,

¹ The New Donation Measures were enacted in August of 2015 but publicly announced by NHFPC only in October 2015 for unclear reasons.

companies, and other organizations. While not further defined, this class of organizations presumably includes both foreign non-governmental organizations and other civil society organizations in China, which under Chinese law must be supervised by a Chinese governmental sponsor in order to operate. The majority of healthcare associations (including medical associations²), foundations, and other charities related to this area are supervised by the NHFPC and its local offices, and therefore are subject to the New Donation Measures.

The New Donation Measures do not specifically state that other forms of sponsorships and grants are included in the definition.

Limitations on the Purpose of the Donation

The New Donation Measures permit donations for the purposes of (a) reducing expenses for medical treatment, (b) public healthcare education, (c) training healthcare personnel, (d) academic activities, (e) scientific research studies, (f) public infrastructure and equipment for healthcare entities, or (g) other non-for-profit activities.

The New Donation Measures prohibit donees from accepting donations when (a) the donation is contrary to law; (b) the donation involves for-profit commercial activities; (c) the donation appears to be commercial bribes or raises suspicion of unfair competition acts; (d) the donation is linked to the procurement and purchase of commodities; (e) the donation is made for political or other ideological purposes; (f) the donor has certain rights to “economic interests,” scientific research, industry data, or intellectual property rights related to the donation; (g) certain other reasons, such as the donation is the result of extortion from the donor. The New Donation Measures do not offer further guidance on when a charitable activity crosses over into a for-profit commercial activity, or when a donation appears to be a commercial bribe.

Local Administrations of Industry and Commerce (AICs), which enforce commercial bribery laws, sometimes assert that certain donations and sponsorships are *per se* commercial bribery. The New Donation Measures may provide additional support for an argument that a donation is legitimate and *bona fide*, although it remains to be seen whether AICs will accept this argument.

Pre-Acceptance Mechanism

The New Donation Measures for the first time require that healthcare entities establish a pre-acceptance mechanism to evaluate the necessity and feasibility before accepting a donation. Proposed donations should be evaluated in accordance with certain criteria, including, among other things, whether the donation meets the scope of responsibility of the healthcare entity (e.g., the services it provides); whether accepting the donation is necessary; whether the donor’s background and its relationship with the healthcare entity counsel in favor of acceptance; whether accepting the donation is feasible; and whether the donation, if accepted, could be deemed commercial bribes or arose suspicion of unfair business practices. These evaluation criteria effectively amount to a requirement that the healthcare entities conduct due diligence on a potential donor and the proposed donation. The New Donation Measures also

² The New Donations Measures also confirm that branches of medical associations may receive donations, provided the parent association authorizes.

provide that, if necessary, a third-party agency and supervising department, such as NHFPC, can be involved in the evaluation process.

Restrictions on the Acceptance, Use, and Management of a Donation

Legitimate sources” for donations. Similar to the 2007 Measures, the New Donation Measures require a written donation agreement between the donor and donee. In addition to the basic information related to the donation such as the quality, quantity, and value of the donation, the donor must also attest that the funds or property are from “legitimate sources,” a term which is not defined. This requirement appears to have been included to prevent money laundering activities via charitable donations.

Prohibition on designating beneficiaries. The New Donation Measures prohibit donors from designating specific beneficiaries when donations are contributed for academic and other research activities. For example, the donation may be made only to the healthcare entity itself, and not a specific healthcare professionals or to departments with the entity.³ Despite these restrictions, donors can propose the name for their donation projects.

Donation through bank transfers. Donors should remit cash donations through bank transfer; when donors donate property (e.g. equipment), the value of the property should be appropriately evaluated. Fair market value of the property should be confirmed and that valuation should be notarized. Specifically, in order to accept a non-cash donation, the donee is “encouraged” to engage an outside agency to determine and attest to the value of the property. A public welfare invoice (*fapiao*) should be issued to donors when the donation is complete.

Restrictions on management fees. Previously, healthcare entities often charged a management fee for the donations they received. Under the New Donation Measures, the healthcare entities may not use a portion of the donation as a management fee or for payment of salaries or stipends. However, societies and other charitable organizations can agree with donors otherwise in the donation agreement. Foundations should also take into consideration specific requirements under other regulations specifically governing their activities.

Reports on the use of the donation. As previously required, a healthcare entity may use the donation only in accordance with purposes stated in the donation agreement. After the donation is complete, donors are entitled to a reports concerning how the donee has used and managed the funds or property.

Increased Transparency and Audit

The New Donation Measures contain a new section on information disclosure. This section requires healthcare entities to publish their policies and procedure on accepting donations, and the status of donations that they have accepted and used. Healthcare entities shall publish

³ In 2014, the NHFPC issued rules that imposed similar restrictions on funds for clinical research products in hospitals, See *Administrative Measures on Medical Institutions Performing Clinical Research Programs*, available at <http://www.moh.gov.cn/zyygj/s3593g/201410/9bd03858c3aa41ed8aed17467645fb68.shtml>.

information about the receipt of donations on their websites or in other mainstream media. In addition, the New Donation Measures also encourage NHFPC and its local counterparts to build databases of the donations that healthcare entities under their jurisdiction have accepted. Healthcare entities are required to answer public inquiries about their donations.

Finally, the New Donation Measures require healthcare entities to report the donations they have accepted in annual financial statements, and provide detailed explanations of these donations. The New Donation Measures require donees, NHFPC, and other supervising government agencies to conduct periodic audits of donations.

Implications

The New Donation Measures impose significant new and detailed requirements on how donations are to be given and received, and provides strong support for the position that legitimate donations that follow these rules will not be deemed to be improper. The New Donation Measures do not, however, squarely address whether life science companies can continue to sponsor individual healthcare professionals to attend academic events, either directly or indirectly via event organizers or healthcare entities employing such professionals.

The requirement for healthcare entities to publicize donations will likely bring more scrutiny of donations by the public and potentially by enforcement agencies in China and elsewhere. To mitigate these risks, life science companies should ensure that their processes for reviewing and approving donations to healthcare entities in China are robust.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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Comparison of Key Provisions in 2007 Donation Measures and the 2015 New Donation Measures

| <p>2007 Donation Measures⁴</p> <p>Interim Measures for the Administration of the Acceptance of Social Donations and Financial Aid by Healthcare and Health Institutions</p> | <p>2015 New Donation Measures⁵</p> <p>Administrative Measures on Accepting Donations for Public Welfare by Healthcare Entities (for Trial Implementation)</p> |
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| <p>“The ‘medical institutions’ mentioned herein refer to the medical institutions (including traditional Chinese medical institutions, traditional Chinese and western integrated medical institutions and ethnic group medical institutions, the same follows) that are established by law, have independent legal personal status, engage in medical service activities, and the operation of which is not for purpose of making profit.”</p> <p>2007 Donation Measures, Article 2.</p> | <p>“These Measures shall apply to public welfare social groups, foundations and other public welfare social organizations governed by public health and family planning institutions of all kinds and at all levels, health and family planning administrative departments and Traditional Chinese Medicine (‘TCM’) administrative departments at all levels (hereinafter referred to as ‘healthcare entities’)”</p> <p>2015 New Donation Measures, Article 2.</p> |
| <p>“The ‘social donation(s) and contribution(s)’ mentioned herein refer to support and aid in the form of funds or materials willingly provided by natural persons, legal persons and other organizations (hereinafter ‘donator(s) and contributor(s)’) to medical institutions without consideration.”</p> <p>2007 Donation Measures, Article 2.</p> | <p>“For the purposes of these Measures, a donation means the public welfare support and help in the form of funds, materials, etc. provided voluntarily and for free by natural persons, legal persons and other organizations at home and abroad (‘Donors’) to healthcare entities (‘Recipients’).”</p> <p>2015 New Donation Measures, Article 3.</p> |
| <p>“The social donations and contributions accepted by medical institutions shall be mainly used for treatment of poor patients, public health education, medical staff training, medical exchange, scientific research, facilities construction of medical institutions and other public interest and non-profit business activities.”</p> <p>2007 Donation Measures, Article 16.</p> | <p>“Healthcare entities may accept public welfare donations if they are used for:</p> <ol style="list-style-type: none"> (1) The reduction and waiver of fees for medical treatment of patients at health organizations; (2) Public health services and health education; (3) The training and education of health and family planning personnel; (4) Academic activities in the health and family planning field; (5) Scientific research in the health and family planning field; (6) The building of public facilities and equipment for health and family planning institutions; and (7) Other not-for-profit public welfare health and family planning activities.” |

⁴ Unofficial English translation from Westlaw. Because the same Chinese terms can be translated somewhat differently from Chinese into English, English translations of the same term may be slightly different from the Westlaw translation of the 2007 Measures and the Covington translation of the 2015 Measures.

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| | <p>2015 New Donation Measures, Article 5.</p> |
| <p>“The acceptance of social donations and contributions by medical institutions must comply with national laws and regulations, stick to the principle of willingness and no consideration, and be in line with the purpose of public interests, and shall not prejudice public interests and legitimate rights and interests of citizens. The medical institutions shall not accept donations and contributions with conditions that might affect fair competition, and shall not link the acceptance of donations and contributions up with purchase of goods (service), and shall not solicit, apportion or apportion under disguised form any donation or contribution.”</p> <p>“The institutions that assume the task of government health supervision and enforcement shall not accept any form of donation or contribution related to the work of supervision and enforcement.”</p> <p>2007 Donation Measures, Article 3.</p> | <p>“Healthcare entities shall not accept any donation that:</p> <ol style="list-style-type: none"> (1) Does not comply with any provisions of national laws and regulations; (2) Involves for-profit commercial activities; (3) Involves suspected unfair competition and commercial bribery; (4) Is linked to the procurement of goods (services) for the organization; (5) Has incidental rights and claims including economic benefits, intellectual property, scientific research achievement, industrial data and information that are related to the donation; (6) Includes materials that are not compliant with national standards and requirements for quality and environmental protection; (7) Has political purposes and other ideological tendencies; (8) Harms public interests and other citizens’ legitimate rights and interests; (9) Involves any demand, imposed charges or disguised imposed charges; and (10) Any institution that is assigned supervision and enforcement tasks by the government shall not accept any donation that may have any conflict of interest with such supervision and enforcement tasks.” <p>2015 New Donation Measures, Article 6.</p> |
| <p>“Where a medical institution accepts social donation and contribution, the supervision department of the medical institution shall review the donator and contributor’s donation and contribution plan together with the financial department and business department of the medical institution, and render their opinion on whether or not to accept the donation and contribution based on whether the donation and contribution project is of public interest and non-profit nature and whether the project involves commercial bribery and unfair competition, and report their opinion to the leaders of the medical institution for their joint review and approval.”</p> <p>2007 Donation Measures, Article 9.</p> | <p>“A pre-evaluation means a comprehensive evaluation conducted by a healthcare entity after receiving a donation request from a Donor and before accepting the donation. Healthcare entities shall establish a pre-evaluation system for accepting donations.”</p> <p>“Key areas covered by the pre-evaluation:</p> <ol style="list-style-type: none"> (1) Whether it complies with applicable national laws and regulations; (2) Whether it conforms to the healthcare entity’s responsibilities, purposes, business scope, and field of activities; (3) Whether it is necessary to accept the donation; (4) Background and business conditions of the Donor and its relationship with the healthcare entity; (5) Feasibility for the donation; (6) Whether the purpose of the donation involves any for-profit commercial activities; |

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| | <p>(7) Whether the donation involves any suspected unfair competition and commercial bribery;</p> <p>(8) Whether the Donor requests any rights and claims in connection with the donation including any economic benefits, intellectual property, scientific research achievements, industrial data and information;</p> <p>(9) Whether the quality and qualifications of the materials comply with national standards, requirements, etc.;</p> <p>(10) Whether the donation has any political purposes and other ideological tendencies;</p> <p>(11) Whether the donation harms public interests and other citizens' legitimate rights and interests; and</p> <p>(12) Other areas deemed necessary by the healthcare entity.”</p> <p>2015 New Donation Measures, Article 11-12.</p> |
| <p>“Where the medical institutions accept social donations and contributions, they shall sign written agreements with the donors and contributors, specify the type, quantity, quality, value, usage of the donated and contributed property, and the rights and obligations of the parties.”</p> <p>2007 Donation Measures, Article 10.</p> | <p>“A written donation agreement shall specify:</p> <p>(1) The name and domicile of the Donor and the Recipient;</p> <p>(2) The type, quantity, quality, and value of the donated property, and an undertaking about the legality of its source;</p> <p>(3) Intent of donation, restricted or unrestricted; where a donation purpose is specified, a detailed budget or plan shall also be provided;</p> <p>(4) Requirements for the management of donated property;</p> <p>(5) The timeline, location, and method for the implementation of the donation;</p> <p>(6) The rights and obligations of the Donor and the Recipient;</p> <p>(7) How to resolve disputes; and</p> <p>(8) Liability for breach.”</p> <p>2015 New Donation Measures, Article 17.</p> <p>“To accept a donation in cash, in principle, a Donor shall be required to remit the amount to the bank account of the receiving legal person by wire transfer.”</p> <p>“To accept a non-cash donation, a Recipient is encouraged to engage a third-party evaluation agency to determine, confirm and notarize the value of the non-cash donated property.”</p> <p>2015 New Donation Measures, Article 22.</p> |

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| | <p>“To accept a donation, a Recipient shall issue a public welfare donation receipt printed by the finance authorities and carrying the common seal of the receiving legal person as per the amount of the cash actually received or the value of the non-cash donated property, and deliver the donation receipt to the Donor promptly.”</p> <p>2015 New Donation Measures, Article 23.</p> <p>“For a donated construction project accepted by a Recipient, the Donor may receive a credit or propose the name of such project, etc.”</p> <p>2015 New Donation Measures, Article 24.</p> |
| <p>“The medical institution shall establish and improve the filing system about accepting donations and contributions, and make filing management about the plan, review, implementation and completion status of the projects for accepting donations and contributions. Upon end of the accounting year, the medical institution shall include information about the status of the donated and contributed funds and materials accepted during the current year in the annual financial report.”</p> <p>2007 Donation Measures, Article 24.</p> | <p>“After the end of a fiscal year, a Recipient shall give a special account of the accepted donated property for the current year in the annual financial report.”</p> <p>2015 New Donation Measures, Article 31.</p> |
| <p>“The medical institutions must respect the donators and contributors’ intention, and carry out public interest and non-profit business activities in strict accordance with the provisions of the agreements. Where the usage of the donated or contributed property is designated in the agreement, the medical institution shall not change the usage of such property at its own discretion. Where there is a need to change the usage, the medical institution shall obtain consent from the donator or contributor.”</p> <p>2007 Donation Measures, Article 17.</p> | <p>“A Recipient shall respect the Donor’s wishes, and shall engage in not-for-profit business activities strictly in accordance with the Recipient’s purposes and the provisions of the donation agreement, and shall not use the donation for any for-profit activities.</p> <p>If the purpose of the donated property is restricted by the donation agreement, the Recipient shall not change the purpose of the donated property without approval. If there is a need to change the purpose, written consent from the Donor is required.”</p> <p>2015 New Donation Measures, Article 32.</p> |
| <p>“The donated and contributed funds shall not be used as staff bonus and allowance or other individual expenses, and shall not be used as reserve for management fee.”</p> <p>2007 Donation Measures, Article 18.</p> | <p>“A Recipient shall not set aside management fees from the donated property, or list the donated property as salary and welfare expenditures for employees, etc.; a Recipient that is a public welfare social group or private non-enterprise entity governed by the health and family planning administrative department or the TCM management department shall not set aside management fees from the donated property or list the</p> |

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| | <p>donated property as salary and welfare expenditures for employees; the relevant expenditures of a Recipient that is a foundation shall comply with the provisions of the Rules for the Administration of Foundations.”</p> <p>2015 New Donation Measures, Article 35 (6).</p> |
| <p>“The medical institution shall include the information about accepting donations and contributions as well as the use and management of the donated and contributed property in the public information of the institution, regularly disclose such information to the public, and accept the supervision from the staff of the medical institution and the public.”</p> <p>2007 Donation Measures, Article 23.</p> | <p>“A Recipient shall voluntarily disclose the following information to the public:</p> <ul style="list-style-type: none"> (1) Management rules for acceptance of donations; (2) Procedures for acceptance of donations; (3) Management department for the donations and its contact information; (4) Information on the donated property; (5) Information on the use of the donated property; (6) Audit reports for donation projects; (7) Results of performance appraisals for donation projects; (8) Other information required to be disclosed under laws and regulations.” <p>2015 New Donation Measures, Article 41.</p> |
| | <p>“A Recipient shall disclose information about acceptance of donations on its official website or in major local news media.”</p> <p>“A Recipient shall respond to any inquiry or question from the public and from the Donor promptly and truthfully in accordance with the law.”</p> <p>2015 New Donation Measures, Article 43-44.</p> |
| <p>“Upon completion of the donation or contribution project, the medical institution shall timely and voluntarily give feedback about the status of use and management of donated or contributed property, as well as the results of implementation of the project to the donator or contributor. As to the inquiry of the donator or contributor, the medical institution shall make prompt reply based on facts.”</p> <p>2007 Donation Measures, Article 22.</p> | <p>“Upon completion of a donation project, a Recipient shall promptly and voluntarily give feedback to the Donor on the use and management of the donated property and the implementation results of the project, and listen to any comments and suggestions from the Donor.”</p> <p>2015 New Donation Measures, Article 45.</p> |