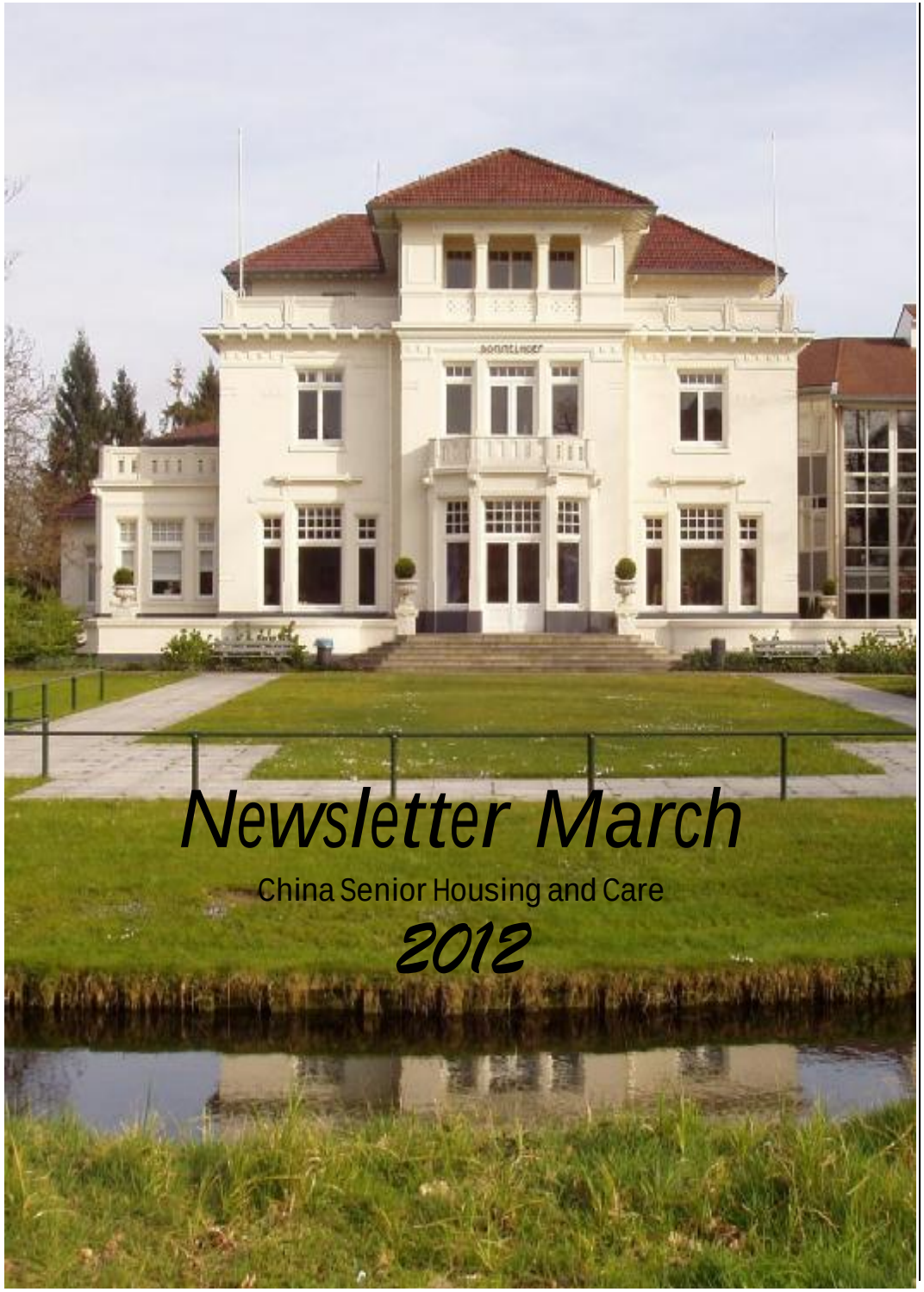

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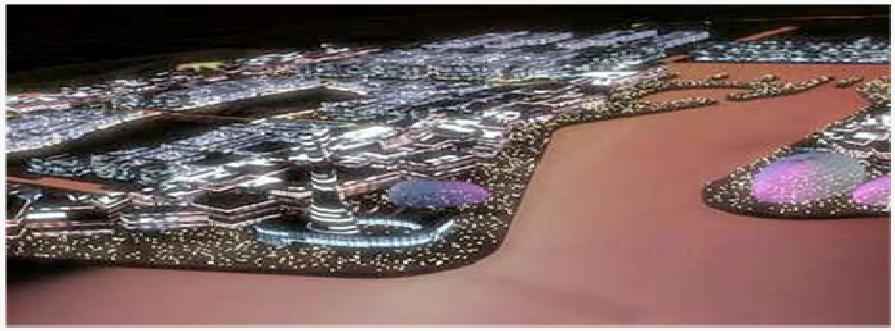
News Update

- **Two Different Types of Senior Community Emerge Respectively in Shanghai and Beijing**



（" Chongming ecological city" planning effect chart）

Senior housing developers are trying different types of business models. Recently we find Shanghai and Beijing are the two most hot destination for senior housing projects, given huge aging population in the two cities.

In Shanghai's Chongming Island, long waited DongtanEcoCity will commerce construction recently. The developer, Shanghai Industrial Investment (Holding) Co., Ltd introduces the whole Ecocity has a total 12.5 square kilometers and will be constructed in a theme of eco, low-carbon and longevity. The Ecocity is planned as a location for senior housing that can reside approximately 50,000 people, and it will be developed by three phases respectively as eastern, southern and northern village. The first phase in eastern village of 2,700 acres, as reported, will be developed as a senior living community in three years and with a total investment of RMB 10 billion. The community will be 1 million square meters, having 7,700 units that can reside nearly 10,000 elderly people.

Depending on the great support from Shanghai NDRC, Civil Affaire Bureau and Health Bureau, it is hopefully to introduce a branch of hospital and a rehabilitate nursing home in Dongtan Senior Living Community, which is also expected to be the biggest senior community in Shanghai by far. With no doubt, this will be a huge test for developer to develop and manage large-scale community in the theme of ecological and senior living. It is also known that a domestic insurance company and a US-based senior care investor and provider will take part in the development and management of the community. As reported, the project is planning to target at people with middle income, providing them with units with one or two bedrooms, either by leasing or purchasing. According to the planning, the community will be

operated as a Continuing Care Retirement Center ("CCRC"), consists of 70% independent living residents and the others will needs care or semi-care service.

On the other hand in Beijing, Vanke, China's largest real estate developer, has launched its first senior housing project for a pilot named Xingfuhui. The project is developed as a residential community in which only 146 units are constructed as senior houses. Constructed as of December 2011 and expected to complete in late 2013, Vanke's pilot of senior housing will be categorized as two types—center for active seniors and senior apartment.

By utilizing commercial land use right within the project, center for active seniors will contain senior homes, utilities for senior services such as medical treatment and psychological consultancy, university, library and gymnasium for the aged. It will also include a 24H call center for in-home care and can provide delivery service of meals or commodities. The senior center will be the developer's self-owned property and is planned to be operated by Cherish Young, a Shanghai-based senior care operator. Senior apartments, on the other hand, designed and constructed suitable for seniors, will be sold in the marketplace. The apartments will be equipped with barrier-free design and remote-control devices for health monitoring.

Whether to develop senior housing as a large community or own and operate as an infrastructure facility of a community, just like development of commercial real estate, is not only a question on business model, but a test on marketing and site location as well. What worth noting is representative from Vanke Beijing says that profitability is not the first priority for its senior housing business, but the cultivation of a mature business model is. In the future, Vanke is planning to place its unique type of senior center and its service in other projects.

- **Senior Nursing –- a Rising and Promising Career**

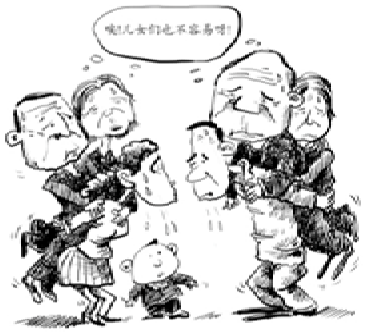
In the wake of China's aging society, senior caregivers are in great demands. As estimated by a 3 to 1 proportion senior population versus caregivers, around 10 million senior nurses are in need nationally. Take Zhejiang Province for instance, as of the end of 2010, senior population over 60 year's old has reached 7.89 million, constitutes 16.6% of the whole population. According to international practice, normally 3% of seniors will need special and skilled care service, which means in Zhejiang there will be 240,000 senior caregivers in demand. However, the situation is senior nursing personnel is in scarcity—only 30,000 licensed senior caregivers in the marketplace of Zhejiang Province.

Then how to fill this blank? Insiders suggested that China's Civil Affaire Bureau can set up short-term and long-term plan to solve the problem—to meet the upfront demand by training laid-off employees in their 40's or 50's and enable them to

provide care service in a short run; and from a long term perspective, to bring up professional staff by using existing facilities and sources of academic and occupational education. Pursuant to China's Nursing Industry Plan of Year 2011-2015, China aims to enhance skilled nursing abilities to provide seniors with long-term care, rehabilitation, healthcare education and hospice; and to formulate nursing protocol and guideline for senior disease, palliative care and hospice. Maybe in the future, more senior caregivers are selected from nurses, a way not only provide nurses with larger career platform, but develop a scaled senior nursing group as well.

Being a new and promising career opportunity for some people, senior nursing are now guided by the newly revised National Occupational Standard for Senior Care Nurses of 2011, where occupational level, training demands and work scope, among others are clearly being stipulated. A foreseeable profession of senior care service is forming, and senior care is no longer an easy job for housekeeper (Bao Mu) or laid-off women.

• Indemnificatory Housing is expected to be another Form of Senior Apartment



In the period of Shanghai's two sessions, delegates from various fields are contributing ideas on construction of senior care industry with regard to expansion of construction on institutional senior care facilities, improvement of insurance market for seniors and encouragement of in-home care service, etc. While exploring new solutions for senior care, delegates raise proposals on developing senior housing in a form of indemnificatory houses. It is suggested to develop large-scale senior communities in Shanghai's suburban areas where many indemnificatory houses are built. With continues improvement of infrastructure such as hospital, school, and transportation, it is a viable solution to plan senior housing in the neighborhood, taken into consideration of the increasing amount of aging population.

Actually this proposal has already been implemented in some cities. From January 1st 2012, city of Chongqing has enforced its local Design Standards on Public Rental Houses, where design of public rental houses shall be abided by the general principle for aging population, and percentage of senior units in the communities shall exceed 2%. On the other hand, Beijing on February 16 published its 12th Five-year Plan on Security Housing Planning to unify construction of senior apartments into public planning. From recent policies, we find it is likely Chinese government will combine development of indemnificatory houses and senior houses as a whole in order to meet huge demands from senior citizens in the years to come.

• Senior Care Institution or Hospital—A hybrid of Both to Meet Senior Care Demands

Recently, a hybrid institutional senior care model with the elements from both hospital and senior care facility is being widely discussed. On one hand from hospitals, many senior patients are unwilling to leave hospital even when they are cured (afraid of being unable to find a bed in case of future sickness), not mention many are uneasy to be cured, cared and prevented from relapse. Therefore, as a result, many hospitals are plagued with seniors who are in need of continuous care. On the other hand from senior care facility, private-owned facilities are mostly without medical qualification, some even with no nurses or professional caregivers. Some facilities are able to corporate with clinics or hospitals, so to arrange on-site healthcare service or therapy on a regular basis; some will set up internal clinic. However, given the unclearness of internal clinic's rule in senior facilities with respect to its function, service scope, personnel and facility requirement, and the fact that most seniors are unable to reimburse from social insurance for medical expenses therein, many senior care operators are trying to establish qualified nursing home in senior facilities or communities according to Basic Standards for Nursing Homes (updated in 2011). However, establishment of nursing home is up to the approval from Health Bureau, and practices are different from place to place. As a result, despite of the current encouraging policies on investment in senior care industry, investors will still very often be prohibited from such establishment in that local Health Bureau wants to control the health care planning and limit the number of medical institutions in the locality.

Therefore, a viable combination of hospital and senior care facility is up on the stage to be explored. The first priority to be solved is reimbursement of medical expenses in senior care facilities. Take Shanghai's situation as an example, currently only less than 20% of private-owned facilities have connected with social insurance reimbursement system. In order to establish such a network for social insurance reimbursement of medical expense, some requirement such as proportion of participants in social medical insurance and bed number in the facility should be met with. Meanwhile city of Qingdao is experimenting a new model of medical care sickroom in the hospital, where seniors with serious disease, being paralyzed or in need of long-term care, can stay in. Expenses arise therefrom will be covered by medical insurance funds, so that if daily expenses are within the reimbursement range, seniors stay in the sickroom are free of medical expenses.

Maybe we can also learn from other countries' experience. For example in Japan, many senior living centers are located near the hospitals. In some hospitals, a special facility will be operated as nursing home, and convenient equipment for seniors are put in place. The hospitals will also assign nurses to take care of seniors and provide physical examination regularly. Expenses either in the hospital or in other senior care facilities in Japan are quite the same, so seniors are more willing to stay in the hospital considering the convenience of medical treatment.

- **Insider Analysis From APBI:**
  China SFDA's Medical Device Regulations

By Seth J. Goldenberg and Esther Zhao

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China is constantly improving its regulatory statutes and bringing themselves in line with other international regulatory bodies, and 2011 was a banner year for regulatory updates from China's State Food and Drug Administration (SFDA).

Significantly, the SFDA started its scheduled enforcement of medical device good manufacturing practices (GMP) regulations, and it also issued new rules that increase oversight of medical device adverse events and recalls. The device approval process was also modified to ease registration by not requiring clinical trial data from companies domestically producing Class II devices, which is very similar to the US FDA 510(k) process.

These changes will have broad implications in the short and long term for domestic Chinese firms and multinational firms already in or considering entry into China.

Enforcing medical device GMPs

With Decree 54, the SFDA officially implemented the new medical device GMP regulations that have been in progress since 2004. These GMP regulations were greatly needed as more than 13,000 medical device manufacturers are currently registered with the SFDA.

The process for these new regulations began in 2004 with a series of seminars, drafting groups, and opportunities for public comment. By 2006, preliminary inspections were conducted based on these guidelines, and by December 2009, the guidelines were officially finalized. This began a one-year grace period for Chinese firms to start implementing the quality and compliance systems to meet these new rules.

The GMPs are divided into 13 chapters covering general risk management procedures, management responsibilities, resource management, documentation, procurement, and other sections standard to international GMP requirements.

The most detailed sections of the new regulations cover production management. The production management guidelines require manufacturers to devise, implement, and document production processes at all steps under their control and formulate guidelines for each device they manufacture. Each product must be marked and monitored during the entire production process to identify and prevent improper use of the device prior to or after official release.

To enforce the new GMPs, the SFDA is using a risk-based approach similar to that used by the US FDA. This means that high-risk devices such as Class III and sterile Class II devices are being prioritized for the SFDA review during the initial inspection and review process. After the SFDA has expanded its inspection teams and processed the backlog of high-risk inspections required during the first phase of this endeavor, other manufacturers can expect to be visited. While no official timeline has been released for completion of the first phase of inspections, they will continue into 2012.

Companies that operate manufacturing facilities in the US or Europe will find many of the new GMP rules familiar. However, multinational firms that source from China, have manufacturing facilities in China, or manufacture and distribute to local markets within China, should carefully review manufacturing processes at their sites, given the increased scrutiny from the SFDA.

Monitoring medical device adverse events

Tracking adverse events and reporting them in a timely manner has been the driving force behind the issuance of Decree 425 from the SFDA. The 45-page guidance document issued in 2011 details requirements for personnel, documentation, reporting times, and annual reports. All medical devices that are registered for sale in China will have to comply with these new requirements. Foreign firms that do not have a China office and are working through local third-party agents and distributors should ensure that their local representatives are aware of, and can comply with, these new regulations.

Each company must have designated staff for reporting adverse events in at least a part-time capacity and a system to properly track, collect, and analyze the root cause of an adverse event. Depending upon the severity of the incident, and prior to a cause being discovered, the sale of the device may be suspended and could require coordination with hospitals and clinics that dispense the device.

For Class III devices, a system must be in place to collect global adverse event data from wherever the device is sold. Severe adverse events must be reported to the SFDA within 15 days, regardless of its location in the world.

The SFDA sets forth detailed requirements for all stakeholders, from device manufacturer personnel to distributors and patients.

Any company whose medical devices are sold in China should carefully review the guidance to ensure that they are in compliance with the guidelines; otherwise, they risk running afoul of SFDA and possible blockage of their product's sale due to improper adverse event monitoring, reporting, or response.

Managing medical device recalls

If an adverse event investigation warrants the recall of a medical device, then the company should follow the Medical Device Recall Management Guidelines laid out in SFDA Decree 82. The decree contains 38 articles laying out the requirements that should be followed in case of a recall.

A recall notice should have:

- Name, batch, and other basic information;
- Reasons for the recall; and
- Recall requirements, such as an immediate moratorium on the sale and use of the product.

Because everyone in the process, from manufacturer to distributor, shares the liability for medical device problems, foreign companies that are working through local Chinese distributors and agents also must ensure that all regulations are being followed properly.

There are three levels of recalls as determined by the SFDA. Recalls are classified as Class I if use of the medical device has caused, or may cause, serious health hazards that are of a permanent nature. Recalls are classified as Class II if a medical device may cause a health issue of a temporary nature. Class III recalls are the least stringent and are used for devices that are not likely to cause harm but are still defective. These recalls can be of a voluntary nature or ordered by the SFDA.

In carrying out a medical device investigation and evaluating its defects, an analysis should be done to determine:

- If the use of the medical device caused the adverse event;
- Whether there is relevant scientific literature, research, testing, or validation to explain the causes of injury;
- Geographical area affected by the damaged device and its population characteristics;
- Extent of the damage to human health;
- Probability of injury;
- Short-term and long-term consequences of the injury; and
- Other potential harm to human health.

While medical device manufacturers and distributors never expect a recall, it is important to review their policies and procedures to guarantee that a recall can be carried out as mandated by the SFDA.

Exemption from clinical trial data requirements for Class II devices

In November 2011, the SFDA issued Decree 475, exempting several types of domestically produced Chinese products from clinical trial data requirements. These clearances are very similar to the exemptions listed in the US FDA's Section 510k.

During the application process, a manufacturer may request exemption from clinical trial data requirements by demonstrating the similarity of their device with an approved product already on the market. The list of products that qualify for this exemption is currently limited to 21 device groups, including medical surgery tools, syringes, thermometers, ECG machines, ophthalmic equipment, nebulizers, electrodes, sterilizers, protective clothing, dentures, cryogenic tools, and single-use urology equipment.

While at first glance this exemption seems like a big advantage for domestic companies, most foreign firms that register Class II devices are already exempt from SFDA clinical trial data requirements because they can provide safety data from their home countries. In addition, once a company has an approved product on the market, they are typically exempt from clinical trial requirements for future products. In the short term, these exemptions will likely be most advantageous for startup Chinese companies that wish to quickly bring new devices to market; however, in the long term, these regulations may facilitate the de novo development, manufacture, and distribution of medical devices in China by foreign companies.

Toward a global standard

SFDA and other branches of China's healthcare infrastructure are working diligently to bring China's regulatory organization and principles in line with international standards. A few of these changes have been reviewed here in relation to medical devices at the national level; however, there have also been numerous changes in the pharmaceutical and healthcare landscape at both the national and local levels, making it critical for companies to frequently review regulatory regulations prior to, or during, their China market entry.

For example, a few of the drug regulations that have been modified were those that include monitoring of pharmaceutical adverse events (SFDA Decree 81), drug GMPs (SFDA Decree 79), and medical institution quality management systems (SFDA Decree 422).

Healthcare regulations also saw significant changes, including the movement of foreign-invested medical institutions from the "restricted" classification to the "permitted" classification and a decrease in regulatory hurdles for opening healthcare centers.

Keeping up to-date on the regulations in China is increasingly challenging; however, as China's slice of the global healthcare market grows, it is becoming increasingly imperative for multinationals to enter China's market. Therefore, proper planning coupled with a cohesive, flexible, and evolving regulatory strategy will be crucial for success in China.

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• How to Manage Accident Risks in Senior Care Facilities

With rapid growth of institutional senior care, accidents in nursing homes are soaring. According to interview with senior care providers, accidents in nursing homes are far from under control: sometimes elderly suddenly falls down without any prior notice or signal; sometimes goes into a coma even when seated; more often are elderly falls down from the bed while nurses happen to be away. Whereas accident occurs, care providers will have to not only appease relatives of the senior, but also take the risks of assuming huge economic responsibilities. In recent years, lawsuits against nursing homes increase continuously and according to existing results, nursing homes will always hold or partially hold liable for accident responsibility. Then how to avoid or mitigate these responsibilities becomes a big concern for senior care institutions.

Take one recent sentence of court for instance, a senior fell down accidently in the bathroom, but seems unaffected apparently. So the staffs in nursing home did not pay enough attention and take rescue measures or medical treatment. In the end the senior died with complication disease very soon. Even though the senior was an independent living resident, according to his care level, the court still sentenced the nursing home responsible for his death for the reason that the senior care provider had not taken prudent and diligent responsibility to take care of the senior, given the service nature of the provider.

Actually, the particularity of senior care industry brings about a lasting topic for senior care investors and providers on how to avoid or mitigate management risk. We think, firstly, senior care facilities shall be qualified from a hardware perspective; secondly, providers shall form internal regulations and handbooks on responsibilities and practice procedures; and thirdly transfer risk by means of resident contract and insurance policy.

(a) Senior care facilities shall be designed and constructed in compliance with qualifications

With regard to the construction standards on senior care facility, the Code for Design of Buildings for Elderly Persons promulgate by Construction and Civil Affair Bureau in 1999, Construction Standard on Community Day Care Centers and Construction Standard on Senior Care Nursing Homes promulgated by Civil Affair Bureau last year can be referred to. The Construction Standard on Senior Care Nursing Homes specifies construction scale, location, planning, construction specifications, fitting and equipment and interior design with related to the construction of nursing homes, senior apartments and other elderly facilities. It is worth noting that Technical

Guidance for Construction Specification on Intelligence System in Senior Communities drafted by the Center for Housing Industrialization is still seeking public opinions, and standards from the MOHURD is expected to be released in the coming months.

Apart from state-level compulsory requirement, more standards on construction design can actually be learned from foreign experience. For example, a decoration company recently introduces Chinese version of Handbook on Senior Housing Design from Japan, which will be adopted as company practical guide in senior housing. Compare to the senior housing design of Japan, domestic design level definitely need to upgrade, for example in the area of IT technology application. In senior communities of Japan, technology of sensor and interactive equipment are wildly put into use. As far as more humane and practical designs are combined with daily management in senior care facilities, risks for accident can to a large extent be mitigated.

（b）Formulate an overall internal mechanism on practices and procedures

For internal management of senior facility, some practice of US counterparts can be learned from. A typical practice is to set up a position on risk management, so to formulate a risk control mechanism according to its own business. The mechanism can be introduced and adopted throughout the whole process of management, such as provide residency handbook and preserve photos of senior upon move in, registration on visitors, reference check on nurses, filing and feedback on complaint or praise, or even procedure on communication and dealing with public relation in case of management mistakes. Meanwhile, responsibilities for risk management position can cover the areas of recognizing and handling all kinds of risks, training for staffs on risk management and settlement, handling complaints from seniors, collecting and analyzing industrial statistics and cases, and studying on legislative environment and contract drafting.

In the event of accident occurrence, the first principle is to immediately notice the senior’s relatives. Forming a complete and detailed accident report will determinate whether senior care provider can mitigate their risk to the lowest. It is recommended to breakdown the contents of the report to every category such as maintenance faults, file recording, personal injury/skin perfection, service/operation related, assets damage or loss, fall down, and policy/procedures, etc. And every category can have detailed sub-categories to be selected. Take “fall down” for example, whether senior is lying on the ground upon discovery, whether witnesses are available, whether alert button is reachable, whether bed or wheel are locked, or whether accident occurs whilst staff shifting, among others can be listed as breakdowns. A sufficient and complete report presented in time will enable government and people’s court to correctly evaluate the liability of the provider and settle down such an accident.

（c）Legally control the risk

From a Contract Law perspective, risks cannot be eliminated by a seemingly perfect residency agreement or risk disclaimer that excludes responsibility belongs to senior care providers. As we discussed above, service provider holds diligent responsibility for senior residents, and therefore any exemption clauses in order to limit or relieve legal liabilities of service provider is invalid. In case accident occurs, service provider shall prove the occurrence is unpredictable and uncontrollable, and nursing staffs have already delivered diligent care and immediate and proper rescue effort to manage the legal responsibility. So it is of the most importance to acquire and preserve favorable evidence to the service provider at the first spot, which will then become essential factors for the result of a lawsuit.

That being said, there is another solution to the whole industry-- participation of the insurance companies to commercially transfer operational risk, which is also an international practice. Currently, insurance companies are inactive on participation in accident liability insurance in that little insurance premium does not match high amount of damage claims. For some senior facilities with limited capability, it is even harder to find an insurance company willing to provide such an insurance product. Good news is as of this year, Shanghai Social Welfare Association will introduce “residency accident insurance” in all of the city’s senior care facilities, in order to ease the burden of liability risks for the operators. Meanwhile, in order to encourage private senior service and allocate management risks of the providers, other local government will also try to establish a mechanism for risk allocation, or provide subsidiary to those seniors who have purchased senior care service.

In summary, it is a full-round test for senior facility operators to control and eliminate their liability on residency accident. A systematic risk control planning is recommended to be put in place, earlier rather than later.

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