



WEBINAR

TOP TAKEAWAYS

Hospitals & Health Systems Innovation Bootcamp for In-House Counsel

Hospital and health system innovation is accelerating, and lessons learned from recent projects can equip in-house counsel to support and engage in their system's innovation efforts. This nuts-and-bolts "bootcamp" took a close look at topics associated with hospital and health system innovation initiatives, investments and collaborative transactions. We delved into specific structures and trends, and used case studies to identify critical legal and business implications. Read on for select highlights from this insightful session. A glossary of terminology used in these highlights is provided at the end.

1

Innovation Center structures vary in nature, approach and complexity and may change as the innovation strategy evolves.

Under any structure, effective corporate governance of the innovation structure is critical and the structure will inform the governance approach.

2

- Whether organized as a division of a health system's parent or as an entity under the parent's control, having innovation governance and management mechanisms that are separate but appropriately integrated with those of the parent focuses and streamlines decision-making, provides the opportunity to involve both internal and external leaders with valuable innovation investment expertise and experience, and maintains the separation needed to protect the integrity of research and clinical care decisions.

- Having health system leadership sit directly on an independent innovation venture or startup's board of directors has advantages and disadvantages. A director seat gives the health system direct oversight of the system's investment, and that director can offer valuable guidance to a new company. However, this arrangement can create competing fiduciary obligations and associated conflicts of interest for the director.

3

Innovation Centers of all sizes and structures struggle to obtain funding. When establishing or expanding an Innovation Center, health system leadership should consider structural alternatives and operational infrastructure that can support and sustain the center's funding and project goals.

4

Other challenges to Innovation Center success include allocating and prioritizing competing opportunities and resources. The innovation function should be driven by a clear innovation strategic plan that aligns with the system-wide strategic vision and priorities. Other key criteria for decision making around innovation include impact on care quality, the cost and availability of capital, selection of appropriate investors and partners, forecasted return on investment, operational/workflow impact, legal and regulatory compliance considerations, and availability of appropriate expertise and levels of personnel.

Transactions that inappropriately benefit certain investors can create Medicare fraud and abuse and tax-exemption risks as well as conflicts of interest that can result in failure to fulfill fiduciary duties. Particularly with investments in “home grown” innovation, the excitement and enthusiasm in the early planning stages of an innovation venture can cause these important considerations to be overlooked. Good intentions do not eliminate such risks. Resist the tendency to avoid or delay the compliance and conflict of interest due diligence. Thorough due diligence, both at the outset and throughout the entire innovation life cycle, will go a long way to managing compliance and conflict risks that can threaten the integrity and prospects for long-term success.

5

- Do the investors, other funding sources or collaboration partners include insiders such as referring physicians, board members, officers, and/or key donors? Are such “insiders” or any other individual or entity with substantial control or influence over the health system or Investment Entity’s decision-making receiving preferential treatment? Does the venture risk taken by each one align with its potential reward? How much control or other involvement will they have?
- How many hats will health system physicians wear vis-à-vis the investment?
 - Are they inventors?
 - Will they receive royalties or an equity interest?
 - Will they provide research and/or clinical expertise to the innovation endeavor?
 - Will they serve on the board?
 - Will they serve in key management roles of the investment entity?
 - Will they use the innovation in clinical care?
- Will pharmaceutical and medical device manufacturers invest or otherwise provide financial support? If so, what other relationships does the health system have with those companies and how will those relationships be affected?

6

Consider structuring your innovation investments in a way that enables the system to maintain its investment in the overall venture without having to purchase or license any particular product of the venture.

7

The health system should be compensated for taking on downside investment risk early in the innovation lifecycle. Downside risk can be lessened with preferred stock, warrants, convertible notes, safe agreements and other mechanisms, particularly when the system makes an investment before the venture is ripe for valuation. Having an exit strategy in case of material changes to investment company purposes or a massive business model change can also help mitigate such potential investment risk.

8

The timing of and approach to supporting valuations is a critical transaction and compliance planning consideration. Start thinking early about whether the transaction would be best supported by an asset by asset valuation or an entity valuation and whether a fairness opinion is needed. Particularly for managing potential compliance and fiduciary risks, it is important to consider whether the valuation can be done internally or by an external expert in order to support the reliability and objectivity of the valuation.

TERMINOLOGY

Innovation Center

- Centralization of oversight of innovation activities at health system
- May or may not be a separate legal entity

Innovation Company

- Company independent of health system which has developed innovative products or services, in which health system or Investment Entity (or Investment Fund) makes investments
- May be start-up, mature entity, or spinoff of health system
- Often is a vendor to the health system

Investment Entity

- Health system controlled entity through which investments are made in “Innovation Company”
- May be separate from “Innovation Center”

Investment Fund

- Health system participates with co-investors in innovation investments through an investment fund
- Fund can be established by health system or health system co-invests in an already established fund alongside co-investors

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