



Integrated Care Models as a Potential Route for Market Access of Innovative Medical Devices in Germany?

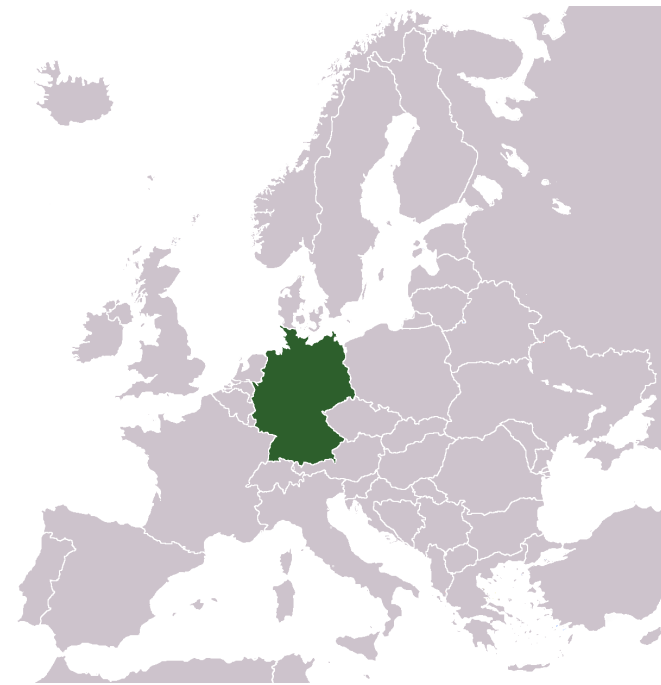
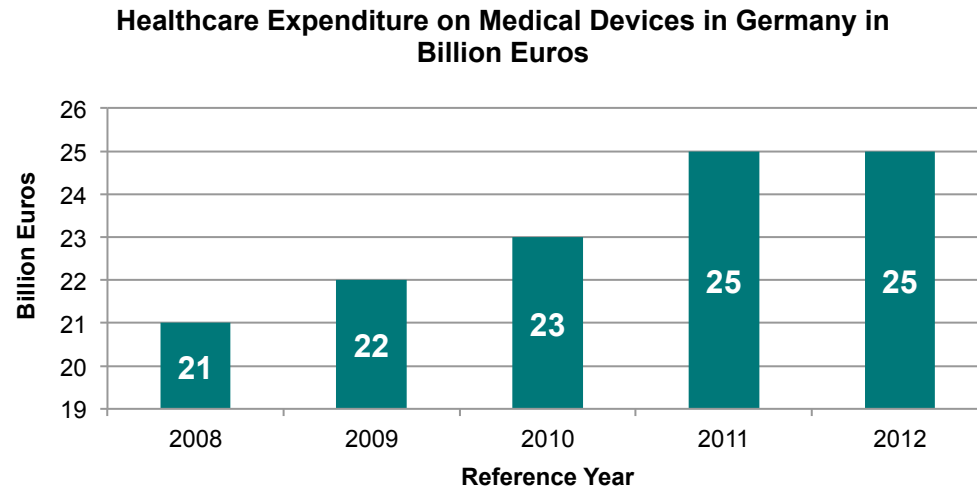
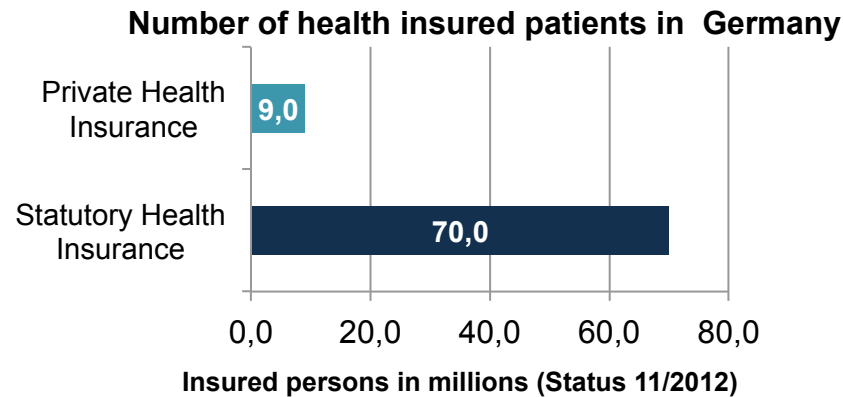
Stakeholder Perspectives on the Concept

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79 Mio Germans have either private or statutory health insurance coverage and in 2012 the healthcare expenditure on medical devices in Germany reached 25 billion euros



For the market access of innovative medical devices in Germany it plays a key role whether a medical device is applied in the inpatient or in the outpatient setting



Inpatient

All **innovative procedures are permitted** with the reservation of prohibition (‘Verbotsvorbehalt‘ SGB V §137c)

Within the hospital (inpatient) new CE marked medical devices can be applied as long as they are not actively prohibited by the joint federal committee

The hospitals are allowed to apply all CE marked innovations

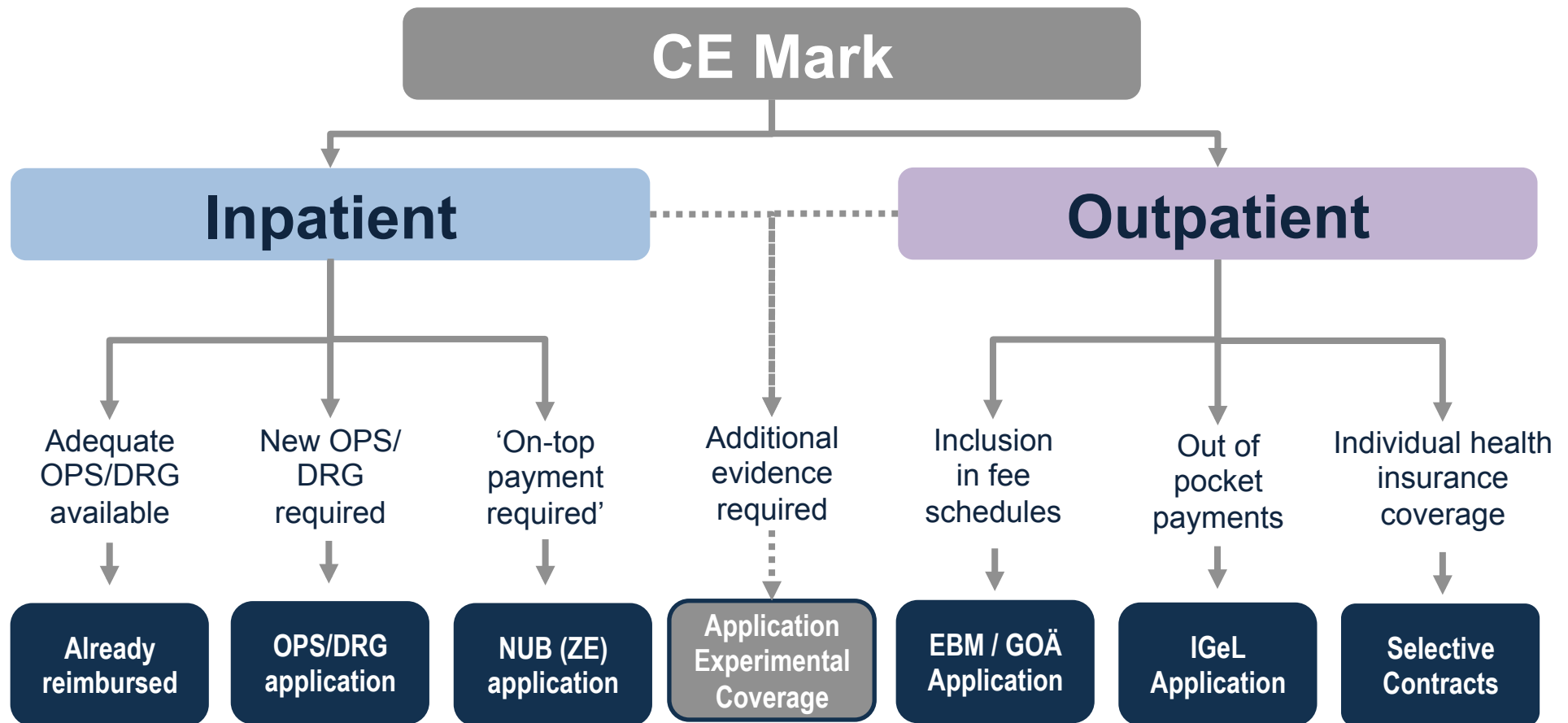
Outpatient

All **innovative procedures are prohibited** until they have been officially approved (‘Erlaubnisvorbehalt‘ SGBV § 135;1)

Before a new medical device can be applied in the outpatient setting a positive voting from the joint federal committee is required

Long application process in order to gain approval for applying innovations

There are several possible reimbursement pathways for innovative medical devices depending on whether a medical device is applied in the inpatient or in the outpatient setting



Managed Care in Germany



- The approach is commonly understood as:
 - A system that applies management principals
 - Integrating fully or partially the financing and the provision of care (only possible as budget based financing)
 - Steering of provisions by selective contracting with selected financers of provisions and providers of care
 - Main Objective/Intention:
 - Reduction of cost or at least level keeping (Cost-Efficiency)
 - At the same time increasing the quality (utility maximizing)

Managed Care in Germany



- The multiple elements of the „Managed Care“ system in Germany for the area of the SHI (GKV) are:
 - GP-centred health care (Die hausarztzentrierte Versorgung (§ 73b SGB V))
 - Model projects in healthcare (Die Modellvorhaben (§§ 63-65 SGB V)) temporarily finite
- Potential other areas dependent on the specific disease are could be...:
 - Special outpatient physicians healthcare (Die besondere ambulante ärztliche Versorgung (§ 73c SGB V))
 - The integrated care/Integrated delivery systems (Die integrierten Versorgungsformen (§ 140a-d SGB V))
 - Structured healthcare programmes e.g. DMP and Case management (Die strukturierten Behandlungsprogramme (§ 137f-g SGB V))

Details of Integrated Care Contracts



- Integrated Care contracts can be set up by
 - all GKV'S (mandatory integral part)
 - all health care providers
 - all management organizations in addition to GKV regular care (collective contracts)
 - Note: This means not an add-on contract but needs rather be settled with budget plans with the KV (physicians organizations)
- The choice of the contractual basis depends mainly on the content design of the selective contract for the special forms of health care
 - e.g. integrated care contracts implies a cross-sector and interdisciplinary care

Goals of Integrated Care Contracts



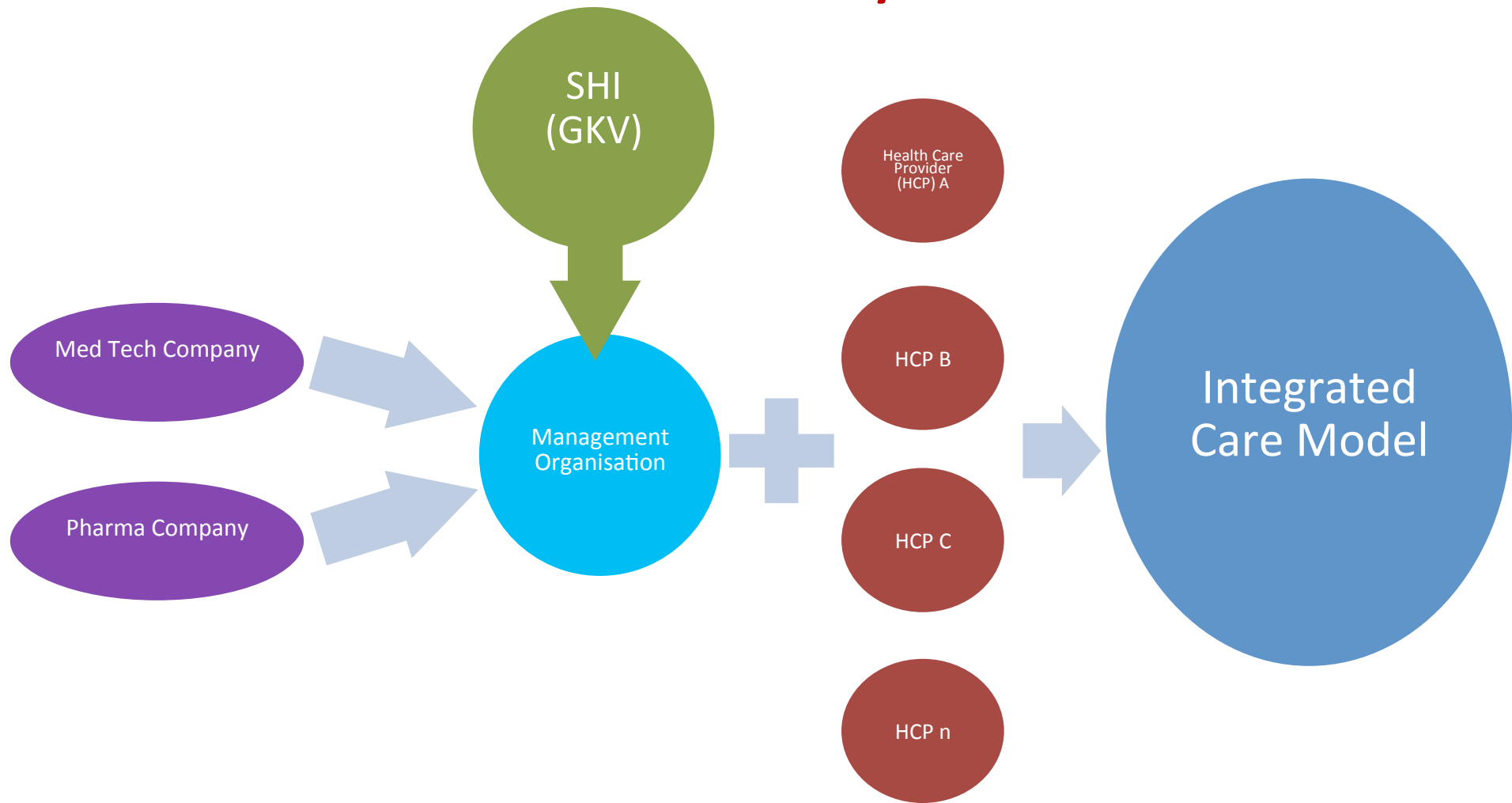
- Goal of a selective contract of any kind is to promote innovative care structures and process within a competitive environment
- The contracts therefore provide comprehensive freedom concerning the content
 - This allows especially to develop and realize new concepts for patient care along with higher quality standards compared to the GKV regular care
- The participation of physicians and patients is voluntary and performed by enrolment
 - Enrolment conditions need to be specified in the contract set-up (speed up process or further hurdle of participation)

Integrated Care overview in Germany



	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>
Contracts (gross)	6 400	6 262	6 374	6 339
Participants	1 661 283	1 635 270	1 771 949	1 926 133
Expenditures (in Mio. €)	1 225 064 973	1 224 214 367	1 353 068 055	1 352 305 185

Integrated care conceptual frame in Germany



Advantages of Integrated Care Concepts



Advantages for Physicians:

- Contractually promoted patient commitment
- Remuneration increases and potentially a higher quality of care

Advantages for patients:

- Availability and utilization of specialized care
- Higher quality of care
- Improved communication and coordination regarding referrals
- Improved healing success and less or prevention of relapses

Key questions remain...



What are the advantages and disadvantages for the...

- **Industry?**
- **Statutory Health Insurance companies?**
- **Association of the Statutory Physicians (KVs)?**



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