

INNOVATION THROUGH COOPERATION

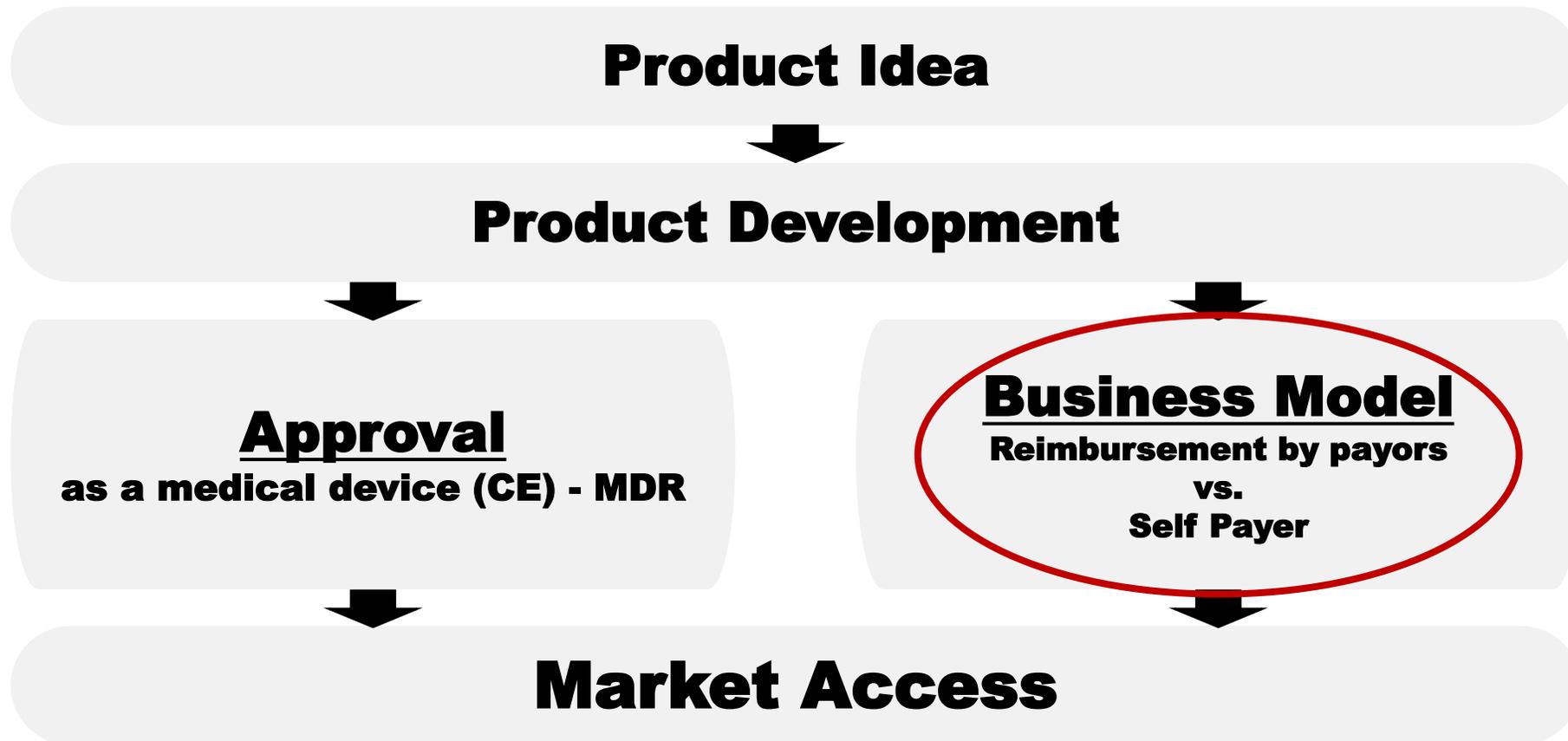
Market Access Germany

28.02.2024



de:hub
digital ecosystems
nürnberg erlangen. digital health

MARKET ACCESS – BASIC THOUGHTS



Agenda



01

German Healthcare Market

02

German Healthcare System

03

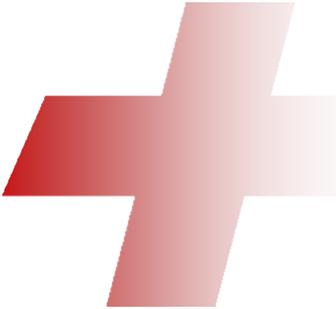
Payment Methods

04

Challenges

05

Pathways of Reimbursement



**GERMAN
HEALTHCARE**
Market

HEALTHCARE MARKET IN GERMANY

84,6
PEOPLE IN
GERMANY

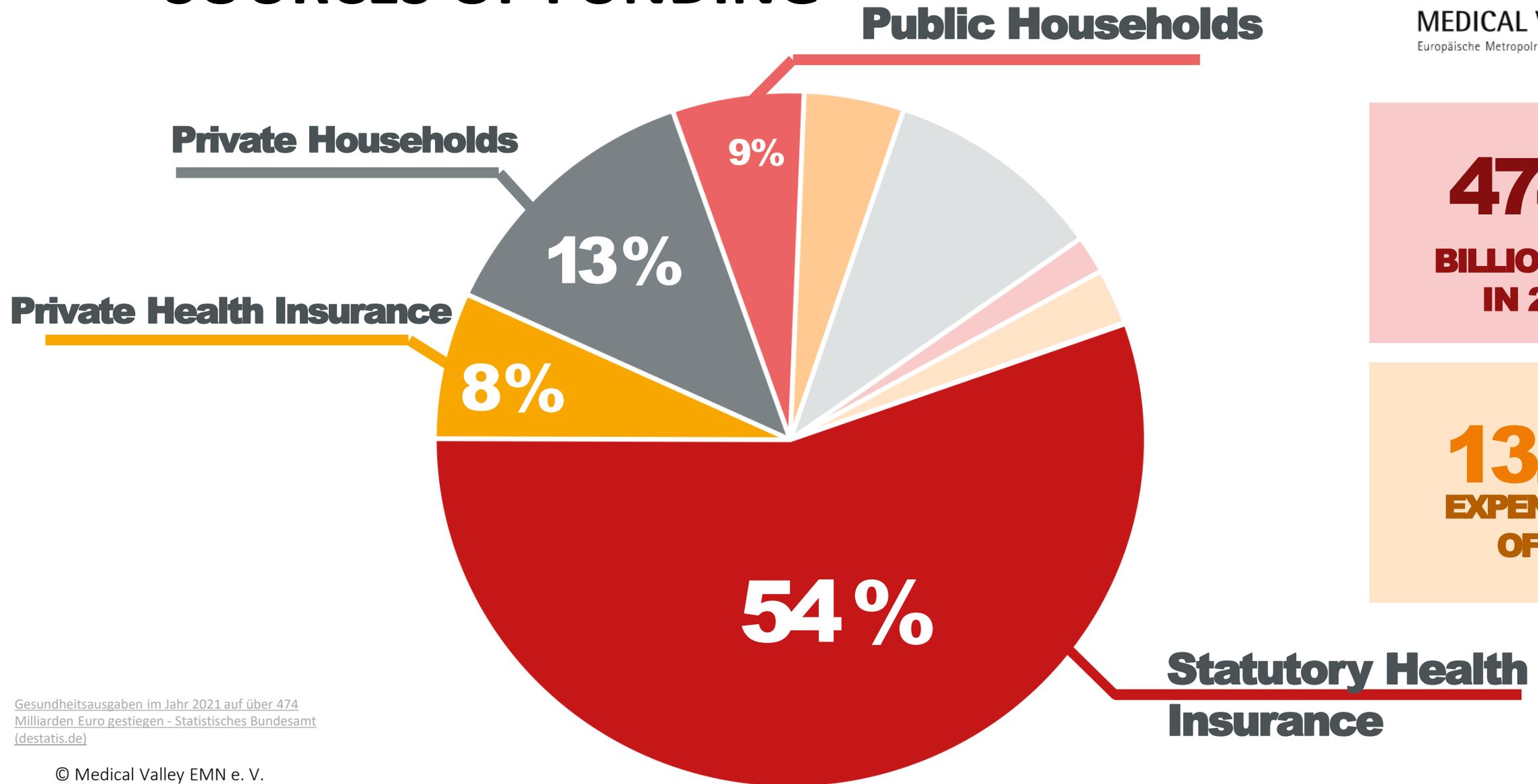
5,699
EUROS PER
CAPITA



474,1
BILLION EURO
PER YEAR

13.2%
EXPENDITURE
OF GDP

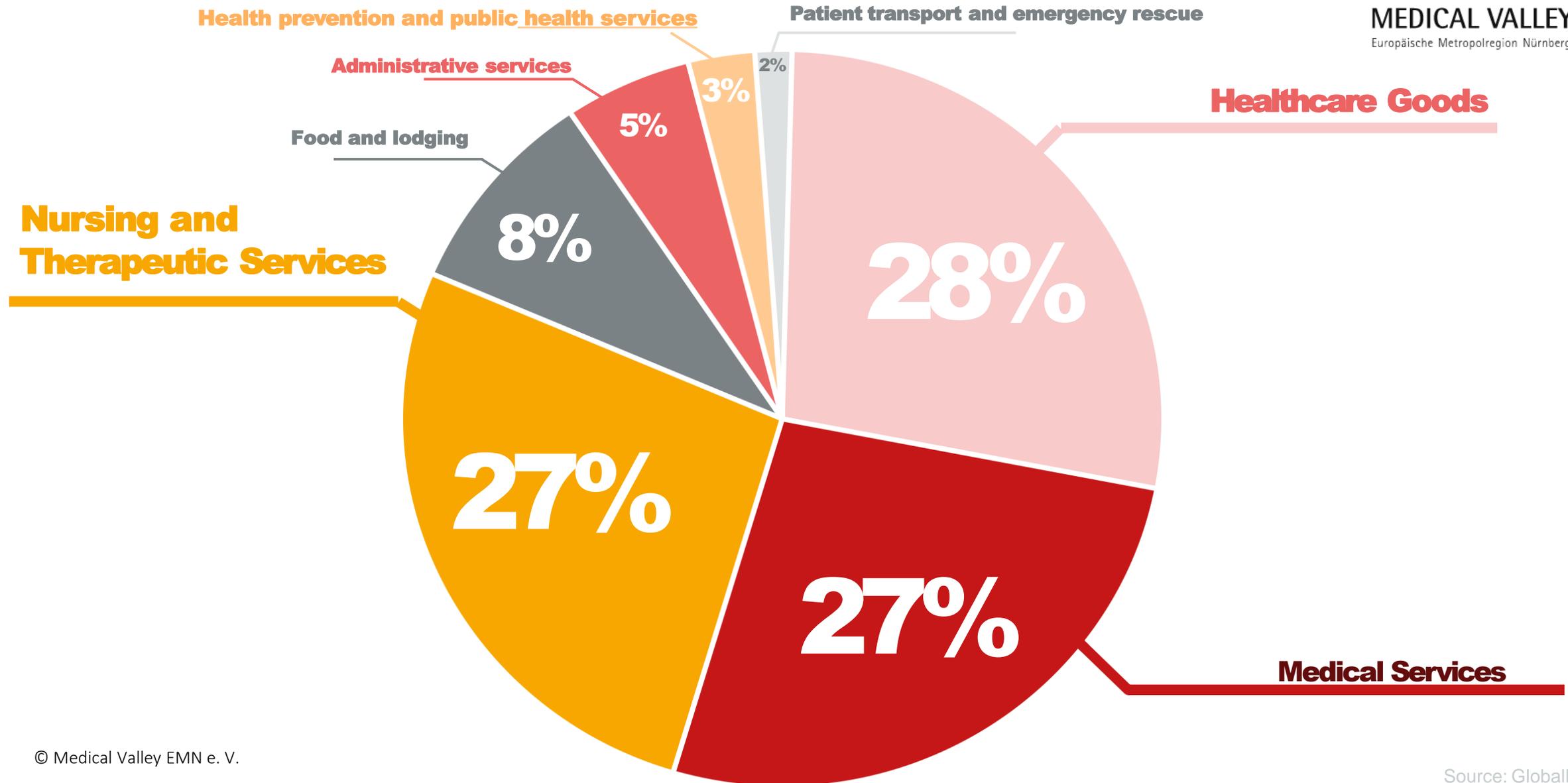
SOURCES OF FUNDING



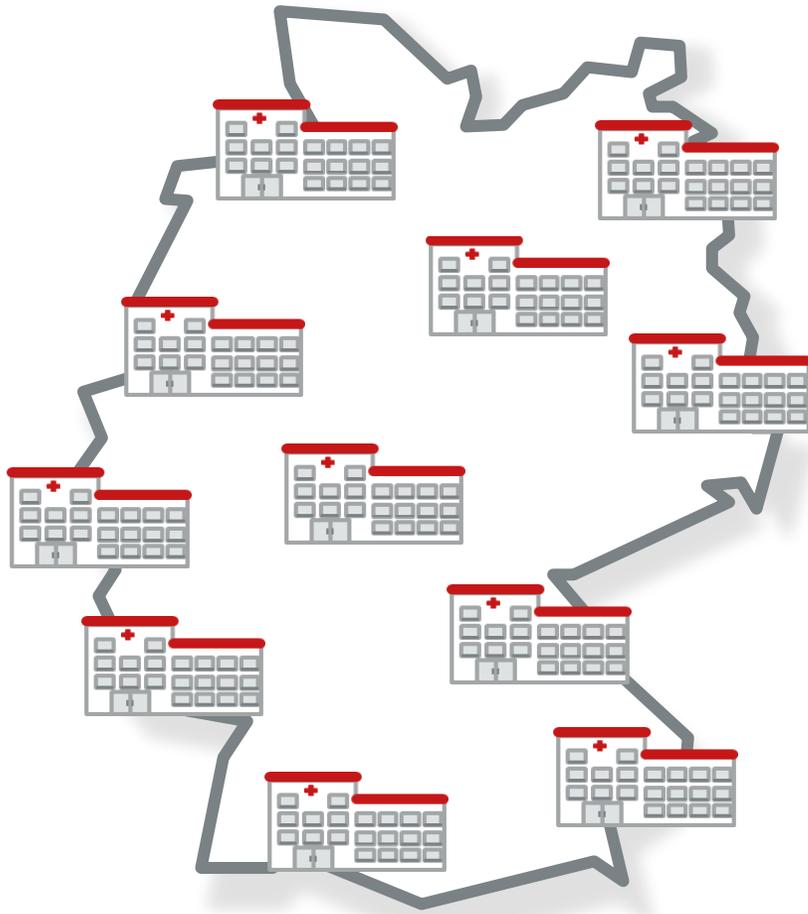
474,1
BILLION EURO
IN 2021

13.2%
EXPENDITURE
OF GDP

MAJOR COMPONENTS OF HEALTH CARE SPENDING



HOSPITALS



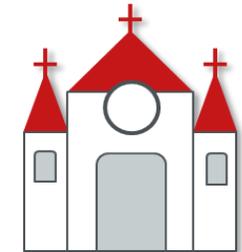
1893
HOSPITALS

756
PRIVATE

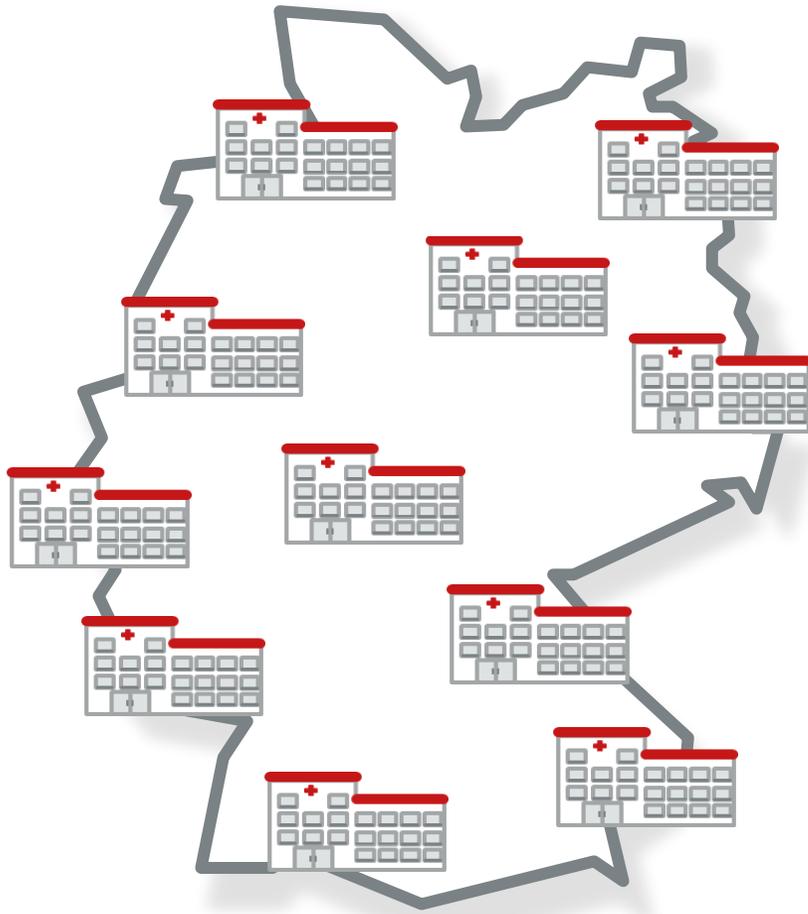


539
PUBLIC

598
NON-PROFIT



PHYSICIANS



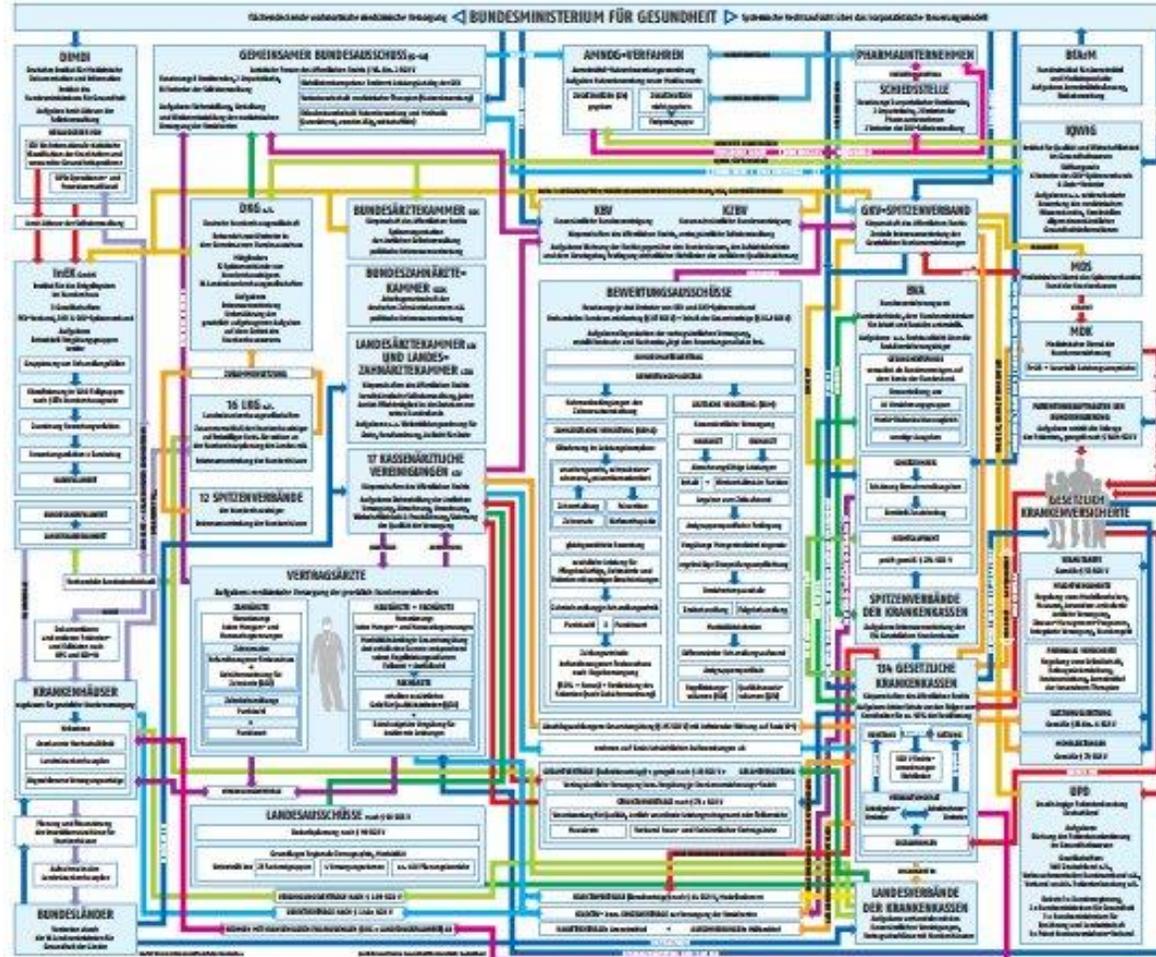
409,121
PRACTICING PHYSICIANS



**GROWTH OF PERSONEL EMPLOYED
IN THE HEALTHCARE SECTOR**

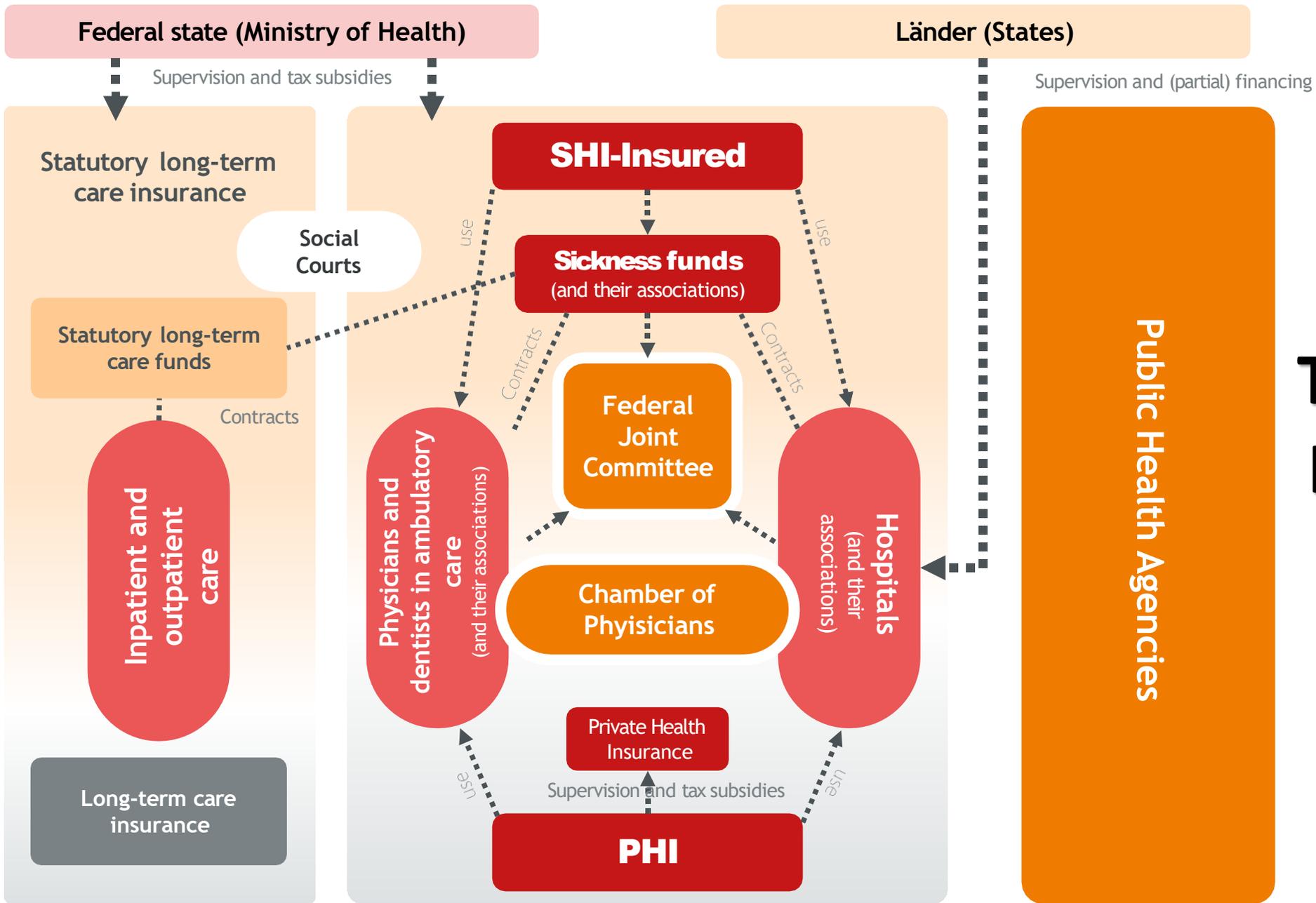


**GERMAN
HEALTHCARE
SYSTEM**



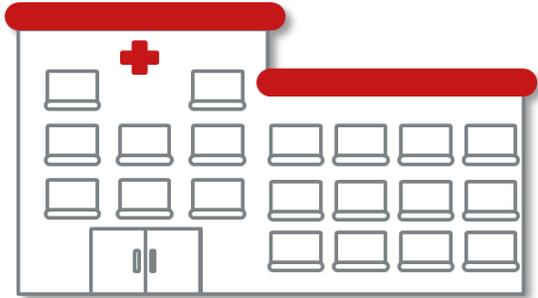
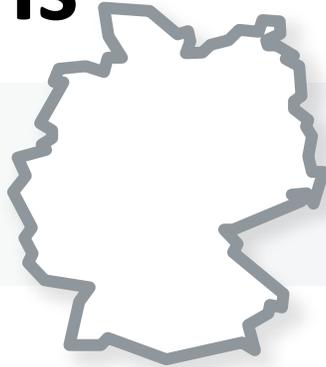
Source: Frankfurter Rundschau

THE GERMAN HEALTHCARE SYSTEM



THE GERMAN HEALTHCARE SYSTEM

Health Insurance is **MANDATORY**



HOSPITALIZATIONS



OUTPATIENT VISITS



PRESCRIPTION DRUGS



DENTAL AND EYE CARE



MENTAL HEALTH



REHA

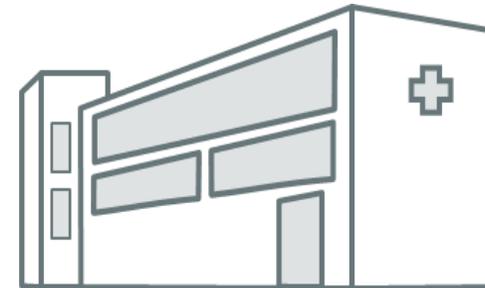


PHYSIOTHERAPY



**GERMAN
HEALTHCARE**
Payment Methods

WHO PAYS FOR THE SERVICE?



**OUT-OF-THE-POCKET
PAYMENT**

**INSURANCE
COMPANY**

REIMBURSEMENT AND PAYMENT METHODS

Primary Healthcare Market

INPATIENT

OUTPATIENT

SHI

STATUTORY HEALTH INSURANCE

PHI

PRIVATE HEALTH INSURANCE

Secondary Healthcare Market



**OUT-OF-THE-POCKET
PAYMENT
SELF PAYERS**

STATUTORY HEALTH INSURANCE

SHI
STATUTORY HEALTH INSURANCE



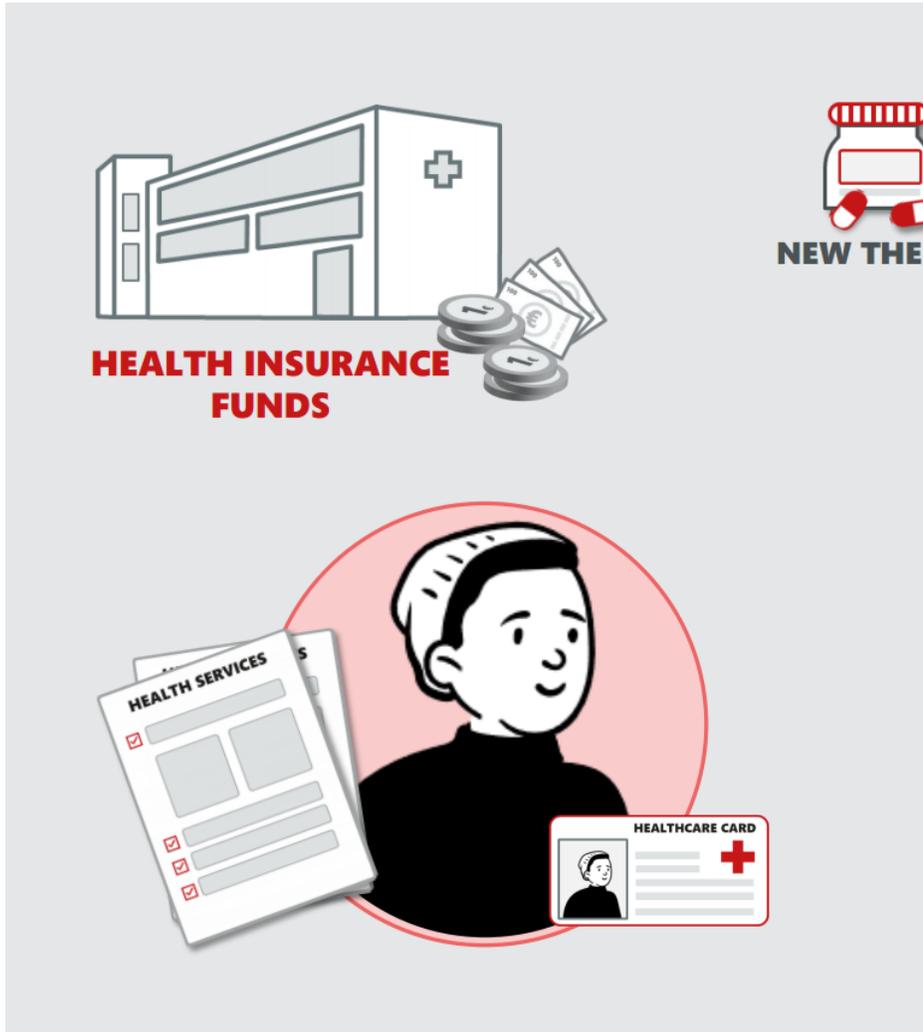
AROUND 100 INSURANCES COMPANIES
CALLED SICKNESS-FUNDS

90%

OF THE WHOLE POPULATION

73 Million

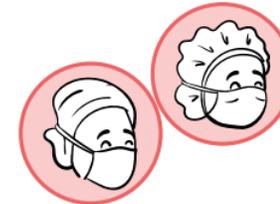
REGULATIONS FOR SHI



FEDERAL JOINT COMMITTEE



SHI COMPANIES



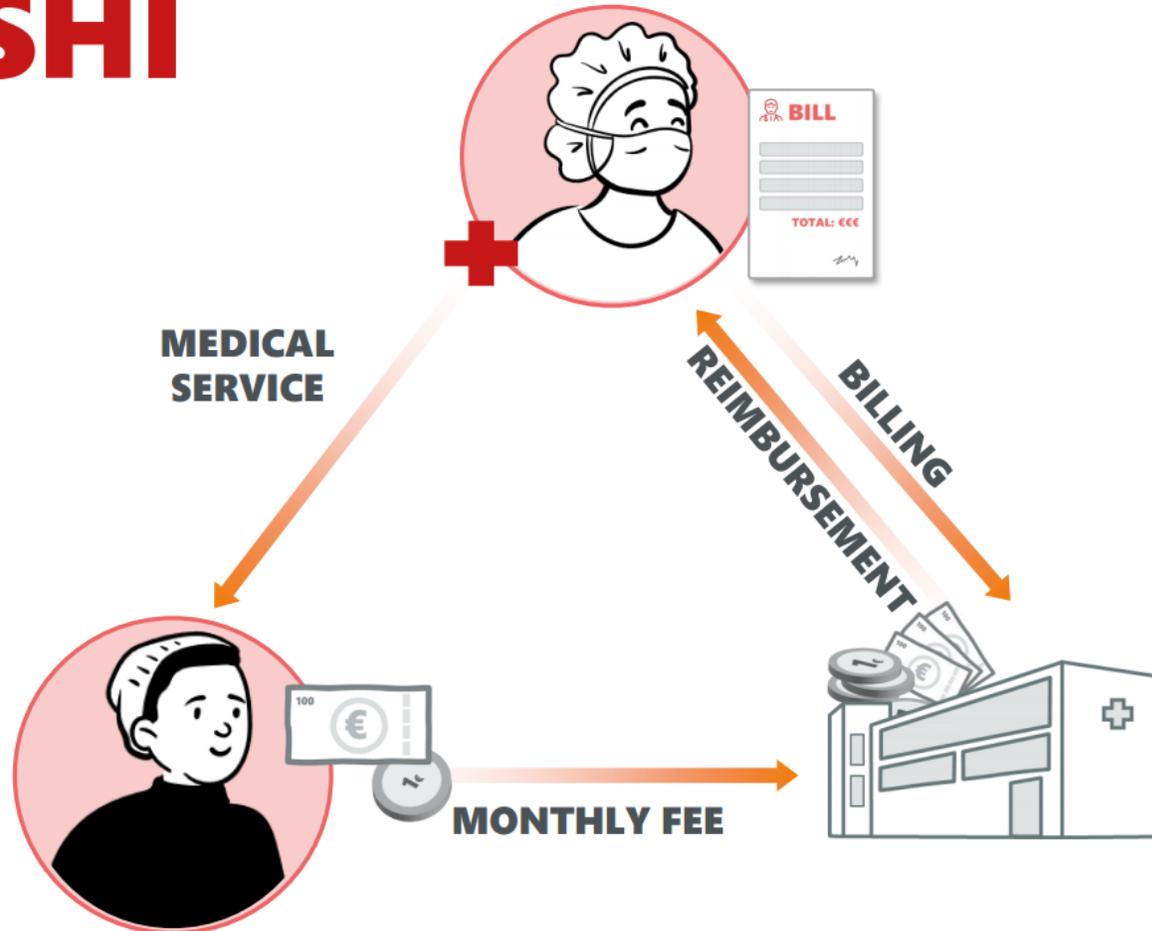
PHYSICIANS REPRESENTATIVES

WHAT TO COVER
HOW TO DEFINE QUALITY

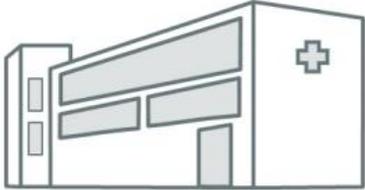
Source: vdek e.V. 2022.; Bundesministerium für Gesundheit 2021a.

FEE-FOR-SERVICE-MODEL

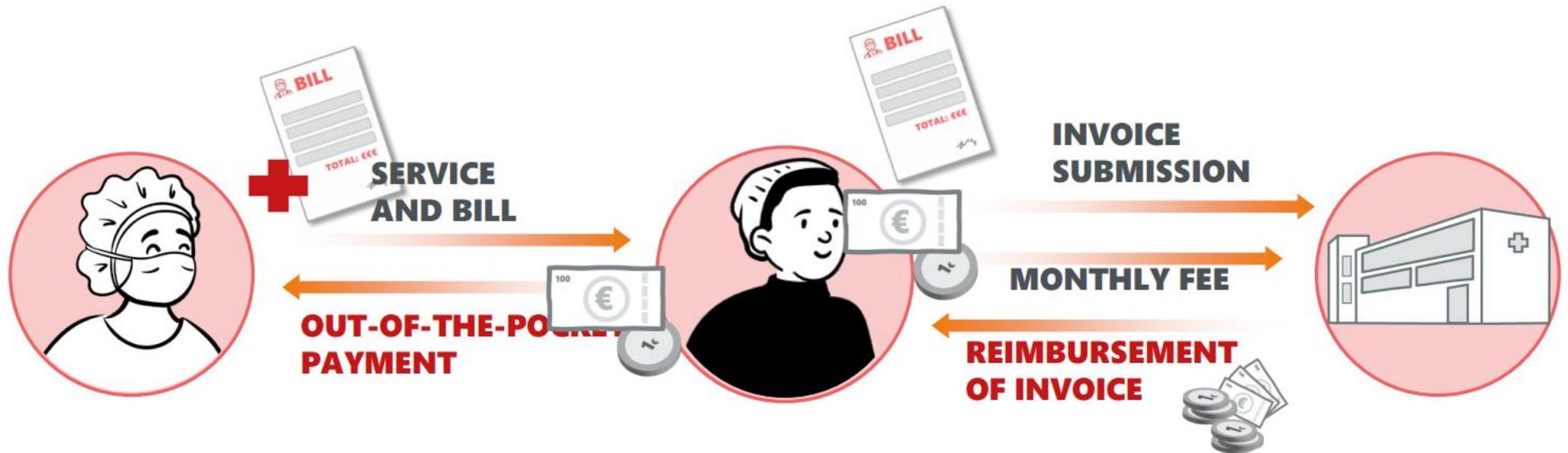
SHI



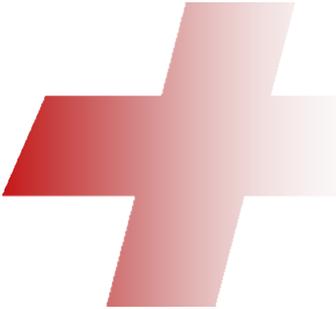
PHI

47 
PRIVATE INSURANCE COMPANIES

10%
OF THE POPULATION

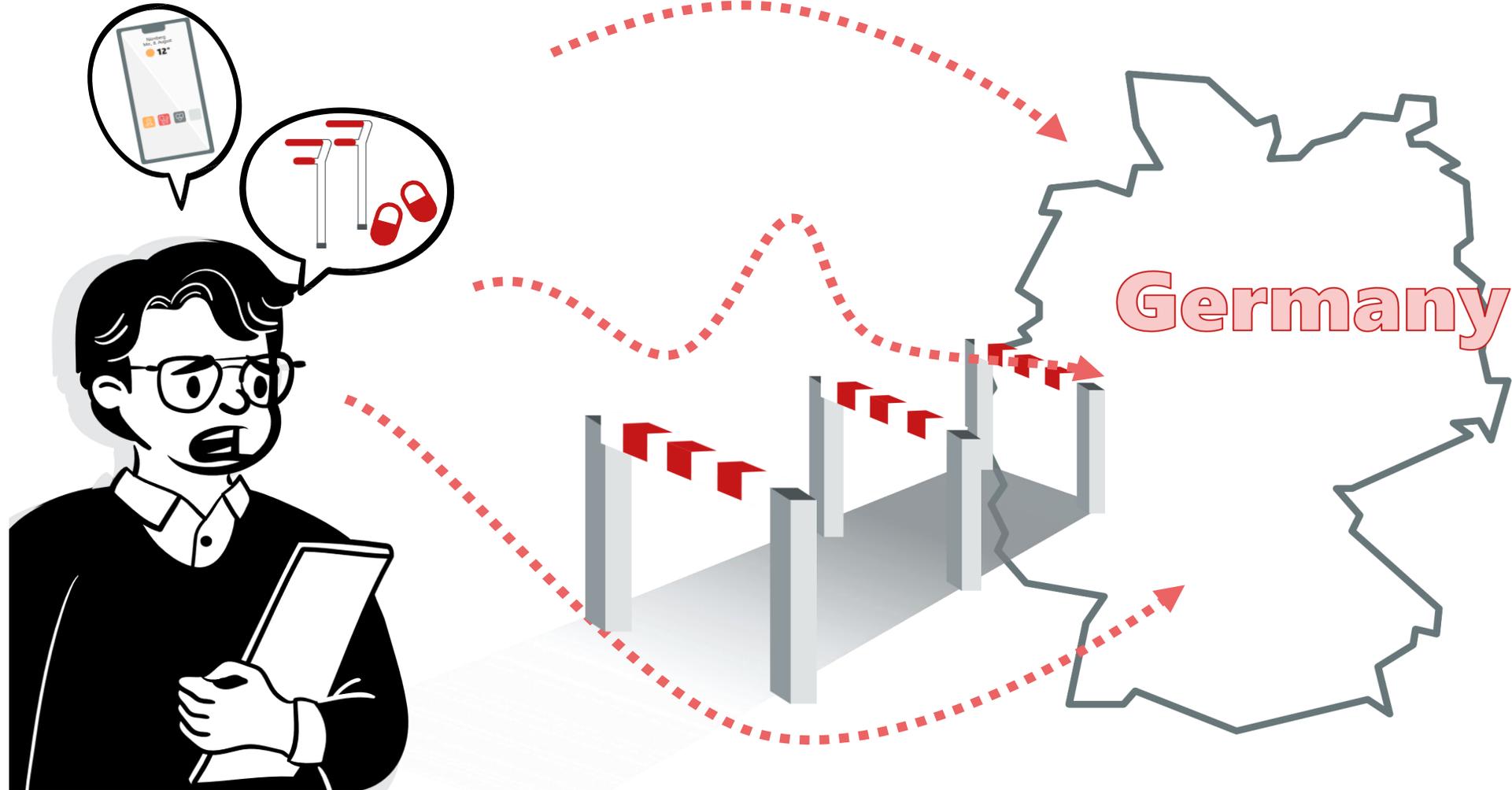


Source: Verband der Privaten Krankenversicherung e.V. 2022.; Bundesministerium für Gesundheit 2022



**GERMAN
HEALTHCARE
CHALLENGES**

CHALLENGES FOR THE MARKET ACCESS



BASIC QUESTIONS



WHO USES YOUR PRODUCT?

WHERE IS IT USED?

WHAT IS IT USED FOR?

**IS THERE A REIMBURSEMENT
PATHWAY AND WHICH IS THE
MOST FITTING ONE?**

WHO PROVIDES THE SERVICE AND WHERE?

Different options to get medical care



**PRIMARY CARE
PHYSICIAN**



HOSPITAL



SPECIALIST

Service can be provided from different members of the healthcare system.



PHARMACY



**MEDICAL SUPPLY
STORE**

Target group

WHERE IS IT USED?

INPATIENT

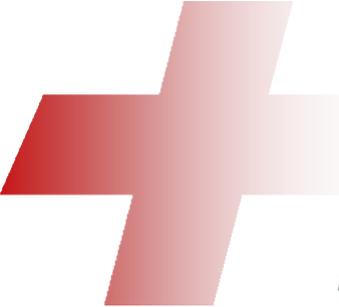
OUTPATIENT



**HOSPITALIZED
CARE**

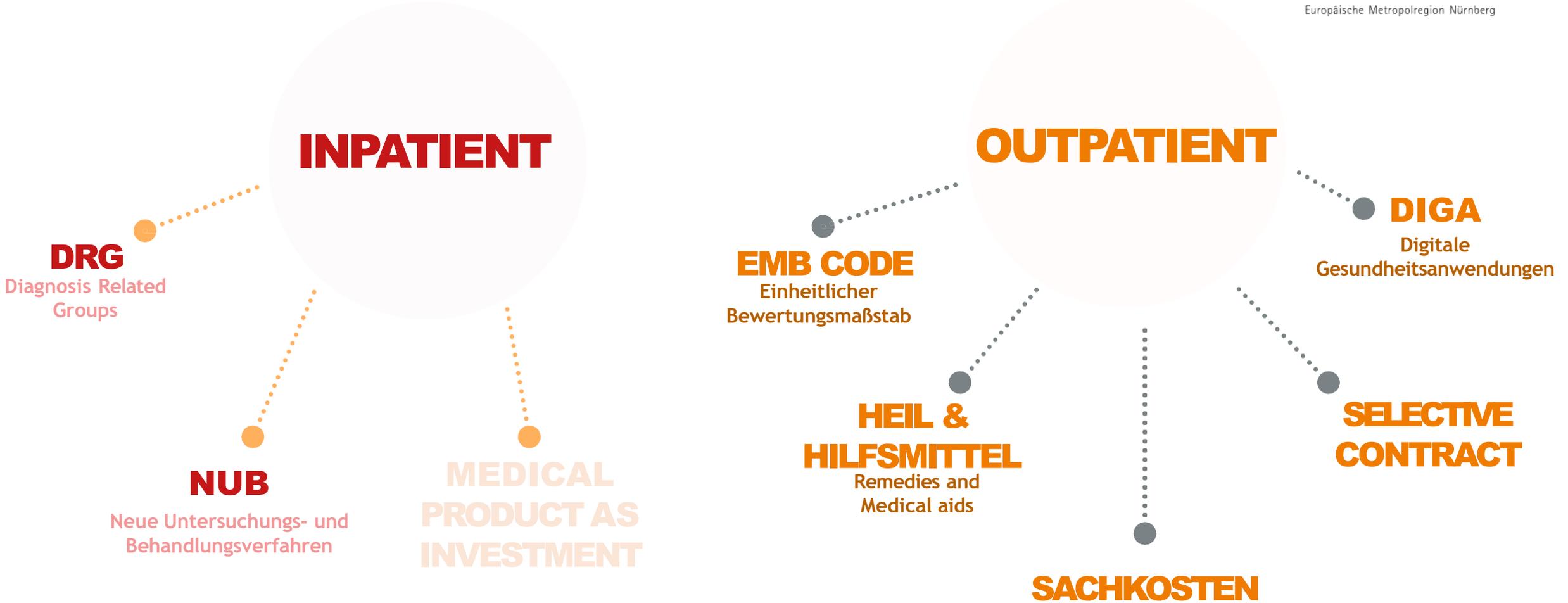


**AMBULATORY
CARE**



**GERMAN
HEALTHCARE**
**PATHWAYS OF
REIMBURSEMENT**

PATHWAYS OF REIMBURSEMENT



INPATIENT – HOSPITALS´ REVENUE

REIMBURSEMENT ACCORDING TO

FLAT-RATE BILLING
DRGs
DIAGNOSIS RELATED GROUPS



HOSPITALIZATIONS



OUTPATIENT VISITS



PRESCRIPTION DRUGS



MENTAL HEALTH



REHAB



PHYSIOTHERAPY

GOÄ
FEES ORDER FOR DOCTORS

INPATIENT – HOSPITALS´ REVENUE

REIMBURSEMENT ACCORDING TO

FLAT-RATE BILLING
DRGs
DIAGNOSIS RELATED GROUPS

GOÄ
FEES ORDER FOR DOCTORS

- ✓ HOSPITALIZATIONS
- ✓ OUTPATIENT VISITS
- ✓ PRESCRIPTION DRUGS
- ✓ MENTAL HEALTH
- ✗ DENTAL AND EYE CARE
- ✗ REHAB
- ✓ PHYSIOTHERAPY



INPATIENT – HOSPITALS´REVENUE

VS **OUTPATIENT**
MORE EVIDENCE NEEDED



PUBLIC HOSPITALS

**PERMISSION WITH
RESERVATION OF
PROHIBITION**

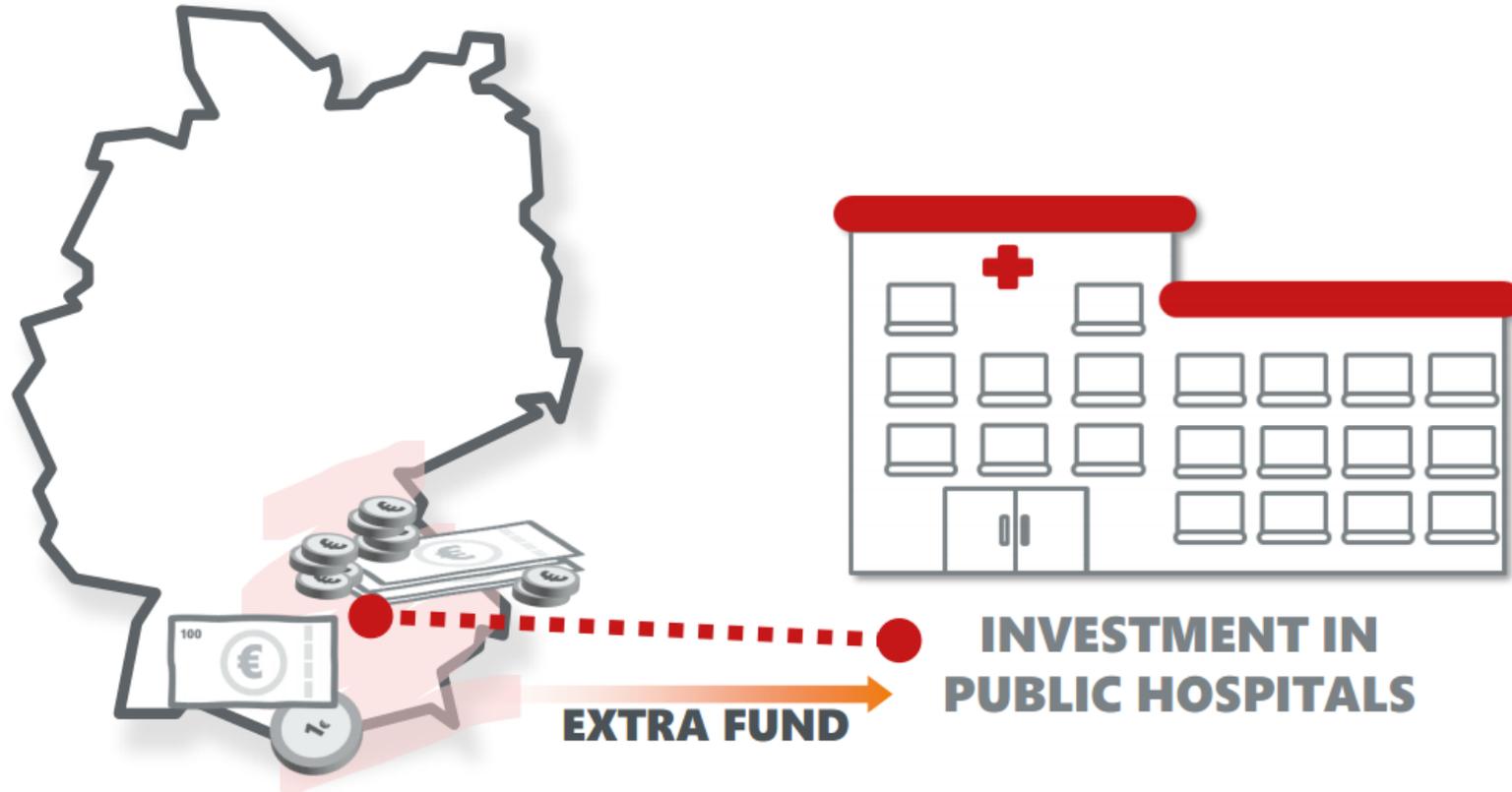
NEW PRODUCT OR TREATMENT

+ TESTED

+ IMPLEMENTED

+ REIMBURSED UNTIL OFFICIAL PROHIBITION

INPATIENT – HOSPITAL INVESTMENT



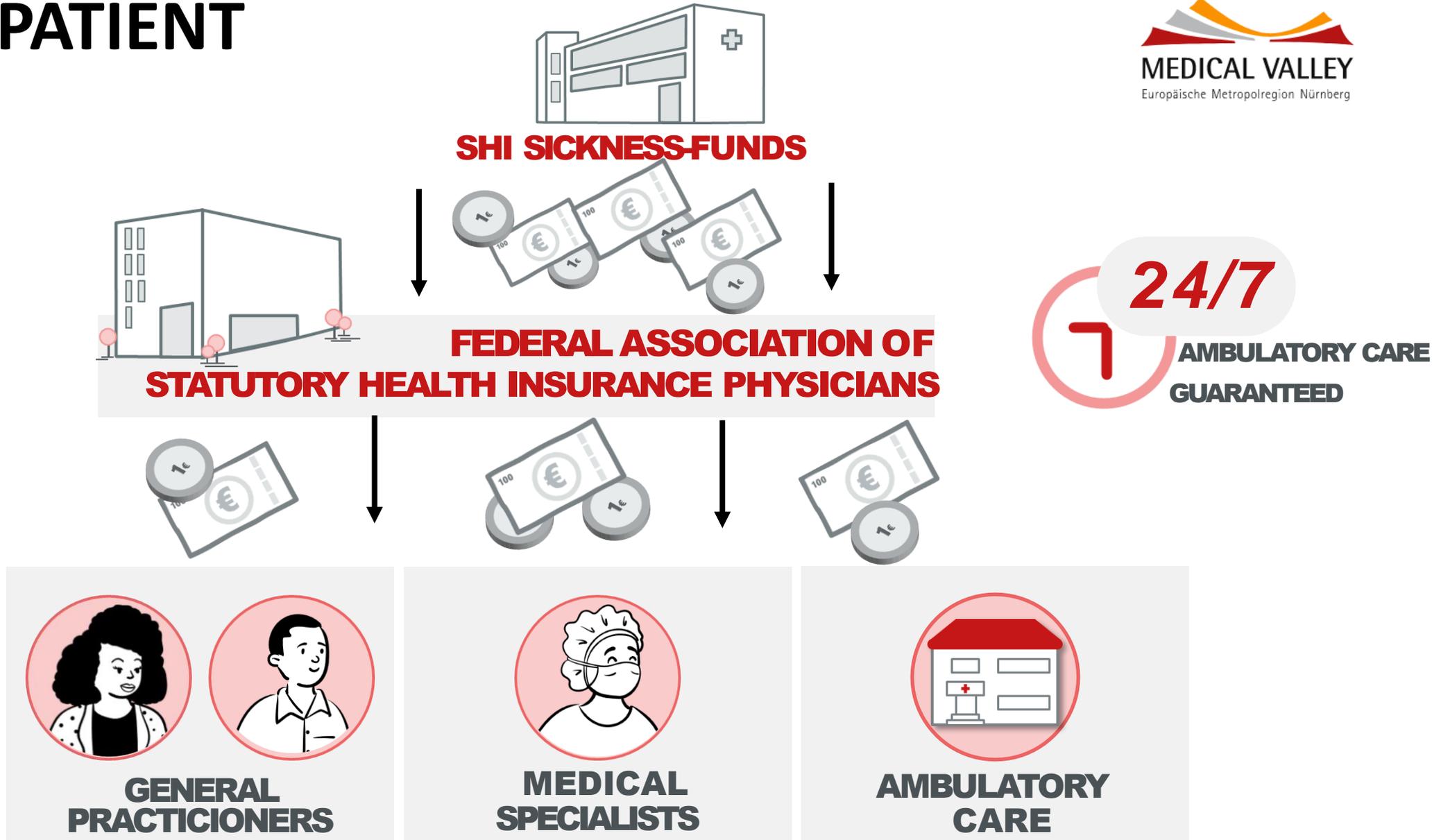
LONG TERM-PROJECT

+ 3 YEARS

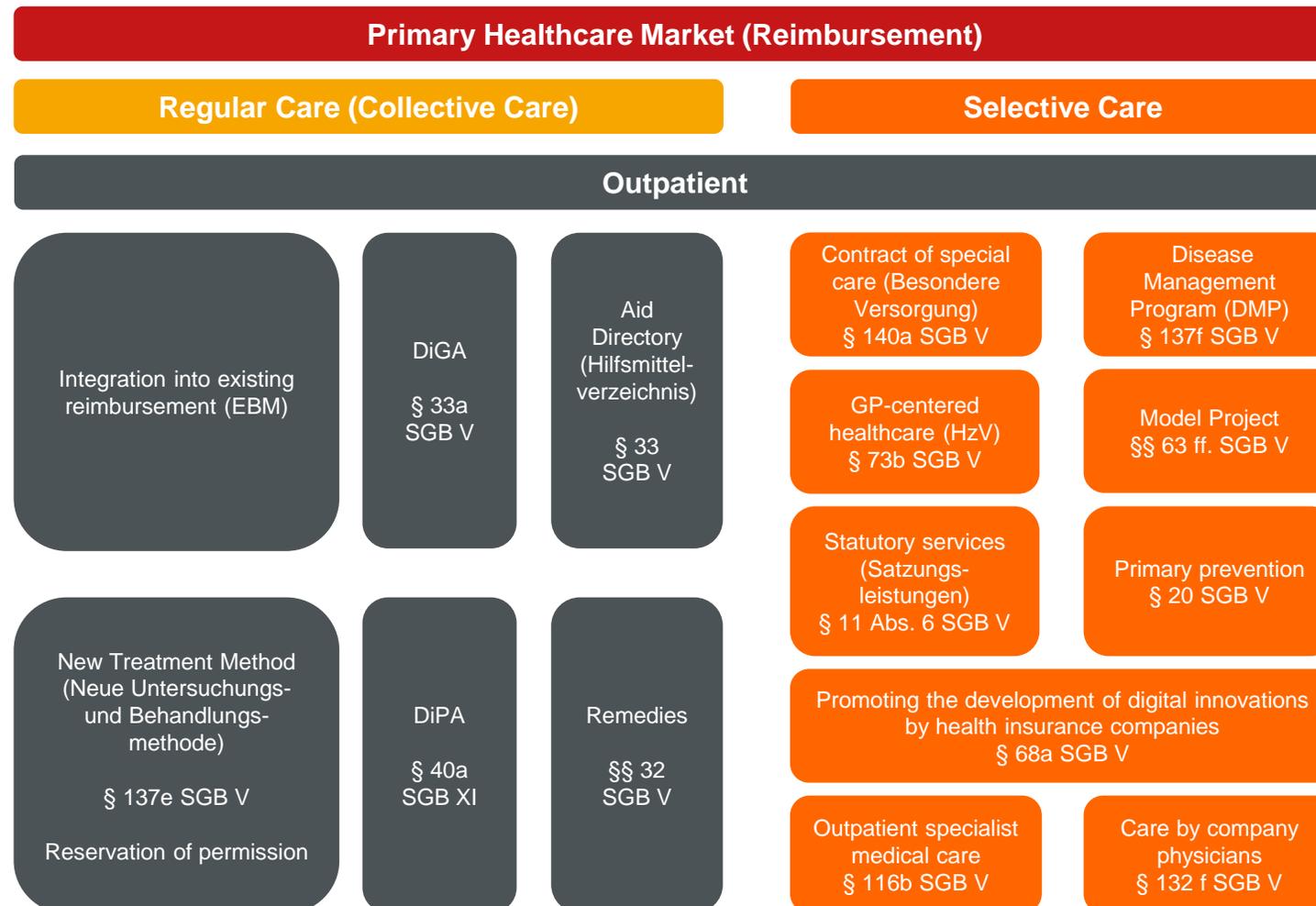
MRIs

CTs

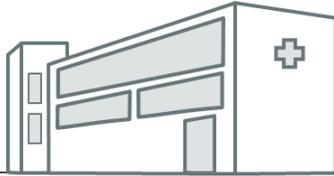
OUTPATIENT



OUTPATIENT REIMBURSEMENT PATHWAYS



Collective Contract - DiGA



Collective Contract (all insurances have to pay for each description)

Scope

Low Risk Medical Device (1 or 2a according to MDR)

Classical App and / or desktop- or web browser solution – combination with hardware possible



Contract Partners

One collective contract

National Association of Statutory Health Insurance Funds

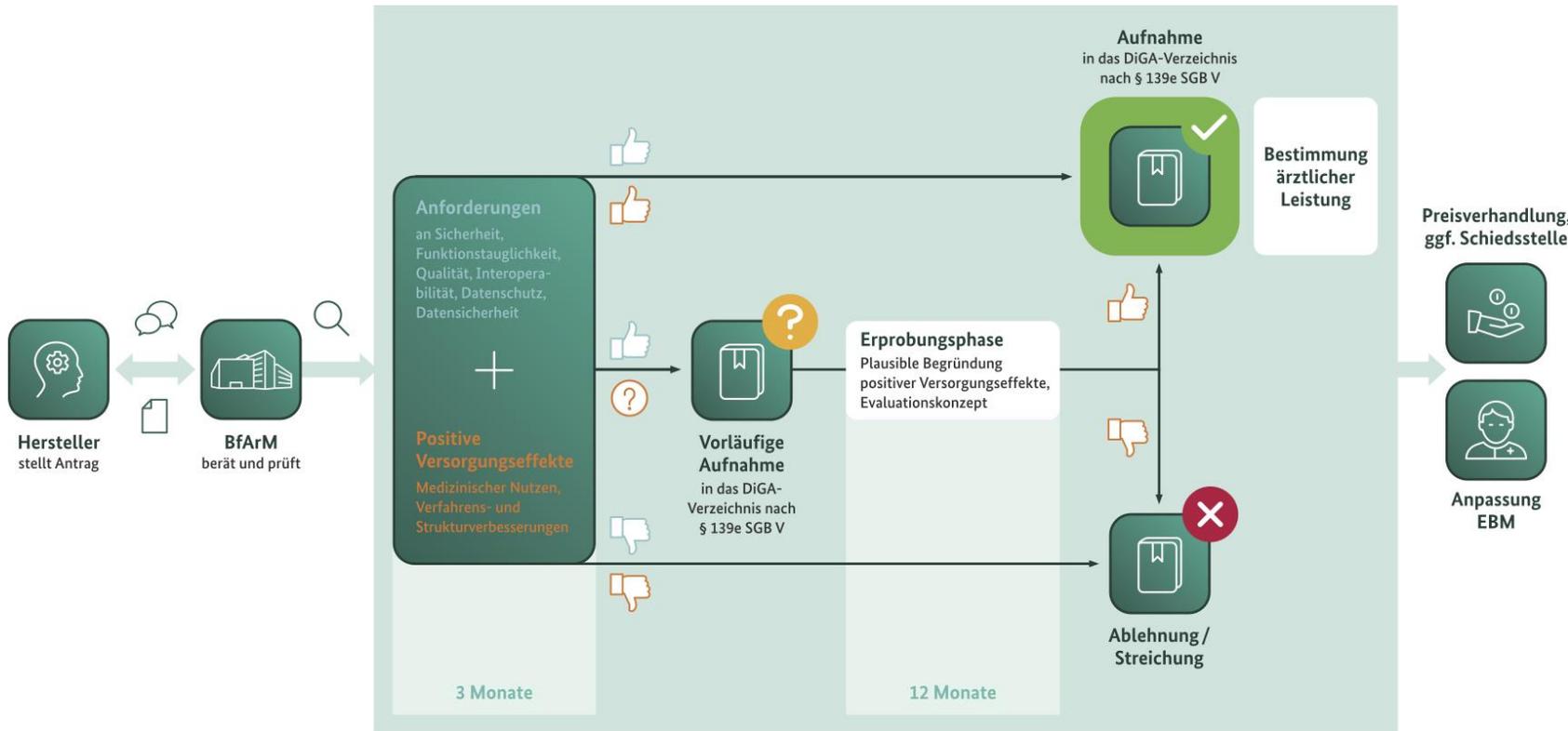


Legal Base

§ 33a SGB V (Standard Care)



Collective Contract - DiGA



Source: BfArM

56 DIGAS LISTED IN DIGA DIRECTORY

374.377 DIGAS USED BY INSURED PERSONS

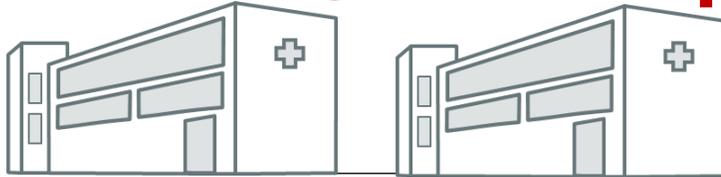
119 – 2.077 € PRICE RANGE

- 65 % PRICE REDUCTION AFTER PERMANENT INCLUSION IN DIGA DIRECTORY

Selective Contracts

SHI

PHI



Contracts with selected health insurance companies (SHI and/or PHI)

Scope

Product or process innovations

Medical Products

Possible product components: hardware, software, medical / physician services



Contract Partners

Statutory Health Insurance

Medtech company

Healthcare providers (not mandatory)



Legal Base

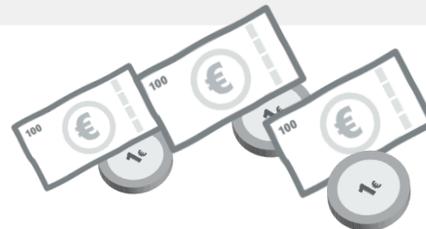
mostly § 140a SGB V (Special Care)

others are e. g. § 11 Abs. 6 SGB V (Statutory services) or § 20 SGB V (Primary prevention)



DiGA vs. Selective Contract

	DiGA	Selective Contract
(Technical) Requirements	Interoperability & usability	Interoperability & usability not mandatory
Evidence basis	Clinical study (RCT)	Clinical studies beyond studies for approval as medical device (CE) not mandatory
Health economic evaluation	Not mandatory	Needed to convince insurance companies
Involvement of medical staff	Combination with healthcare services possible; but main function digital	Yes, please



Wrap-up

- German Healthcare System is quite complex due to the numerous actors involved.
- Germany offers good market chances, especially in the first healthcare market. Self payer market in Germany is in general difficult to adress.
- The optimum reimbursement pathway is always a company individual decision.
- Three questions help:
 - Who uses your product?
 - Where is it used?
 - What is it used for?
- Decision if it is a reimburseable good or an „investment good“ or consumable.
- Knowing the right reimbursement pathways is great, but having a reimbursement contract is just a start. It needs much additional work in marketing and sales to earn money.

Invitation to Webinar: CoP-Reimbursement



Community of Practice: Reimbursement

Thema: Selektivvertrag



19. März 2024, 15:00-16:00 Uhr



Online, MS Teams