Ideas & Solutions

Dávid Dankó, PhD

Madrid, 3 November 2016

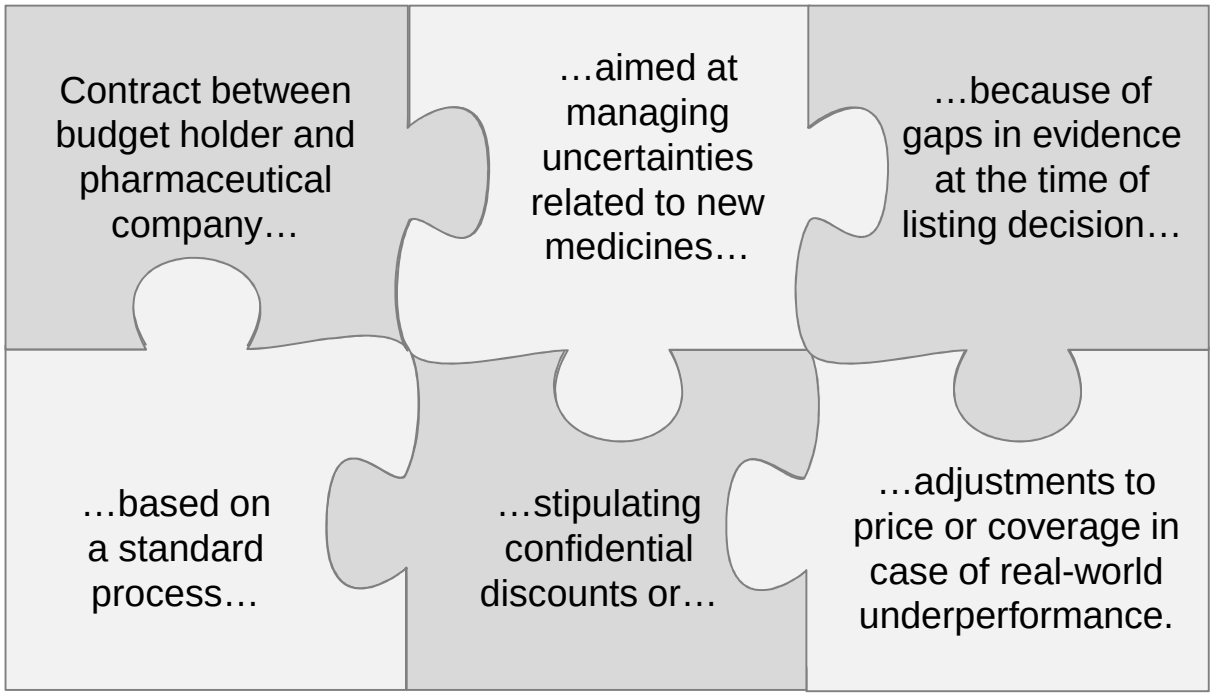
SEFH Managed Entry Agreements workshop

Design and implementation of MEA's in hospitals– a roadmap for hospitals in Spain

H-1118 Budapest, Kelenhegyi út 16/B.

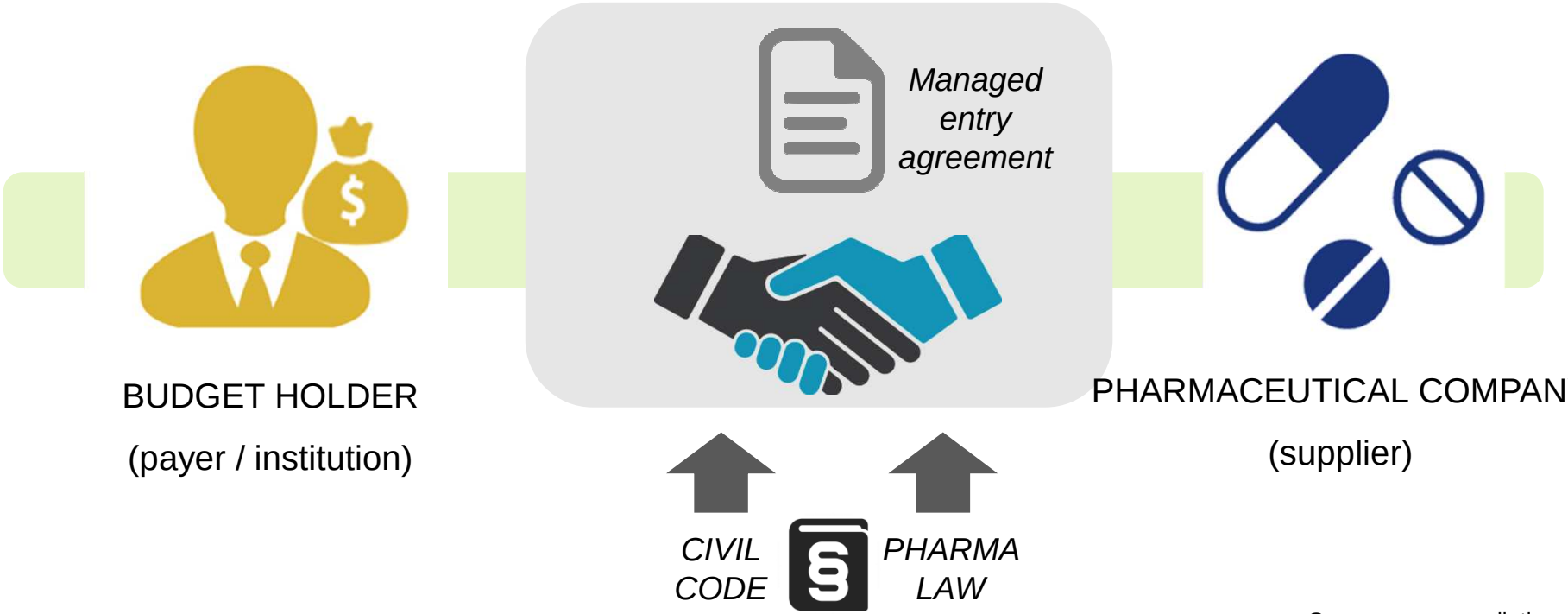
office@i-s.hu
http://www.i-s.hu

Purpose of managed entry agreements



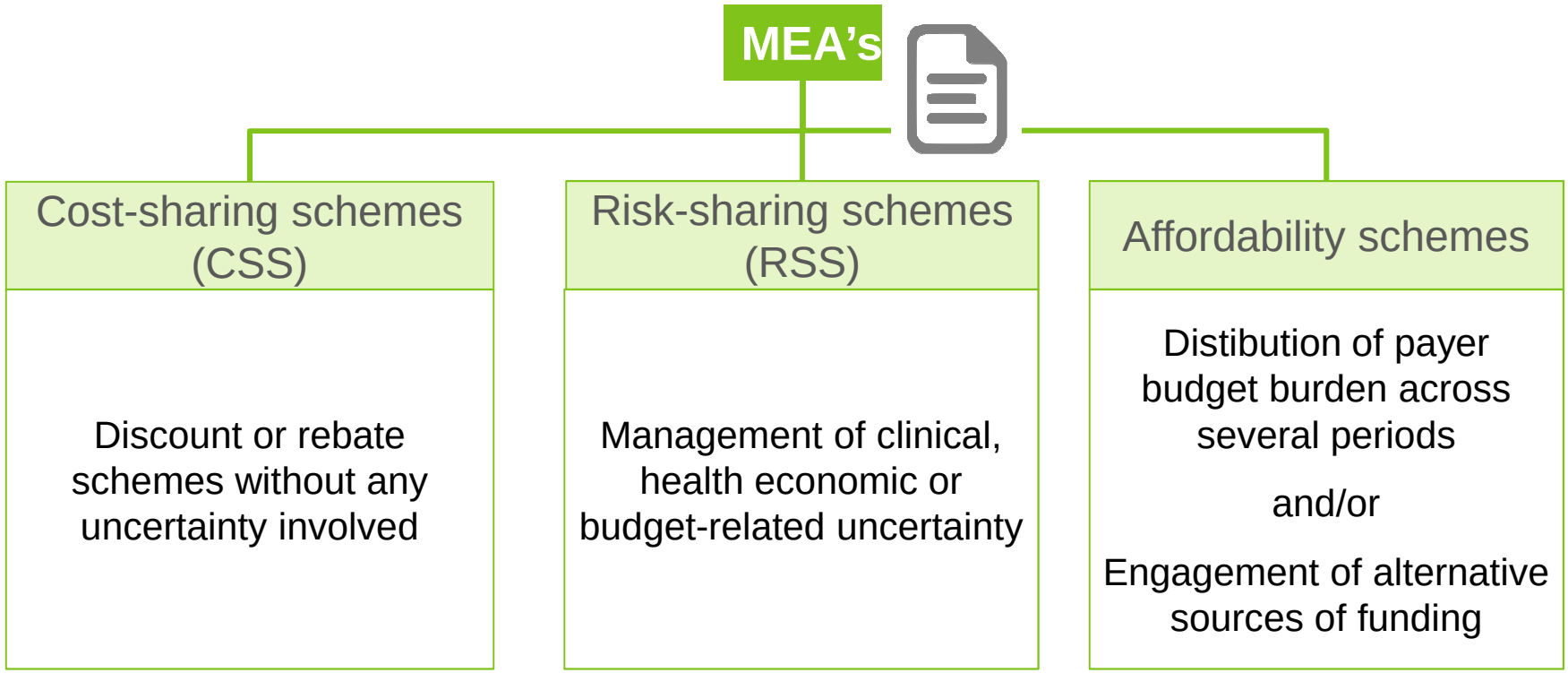
Source: own compilation

Managed entry agreements (MEA's) are contracts, governed by the Civil Code and industry-specific regulations



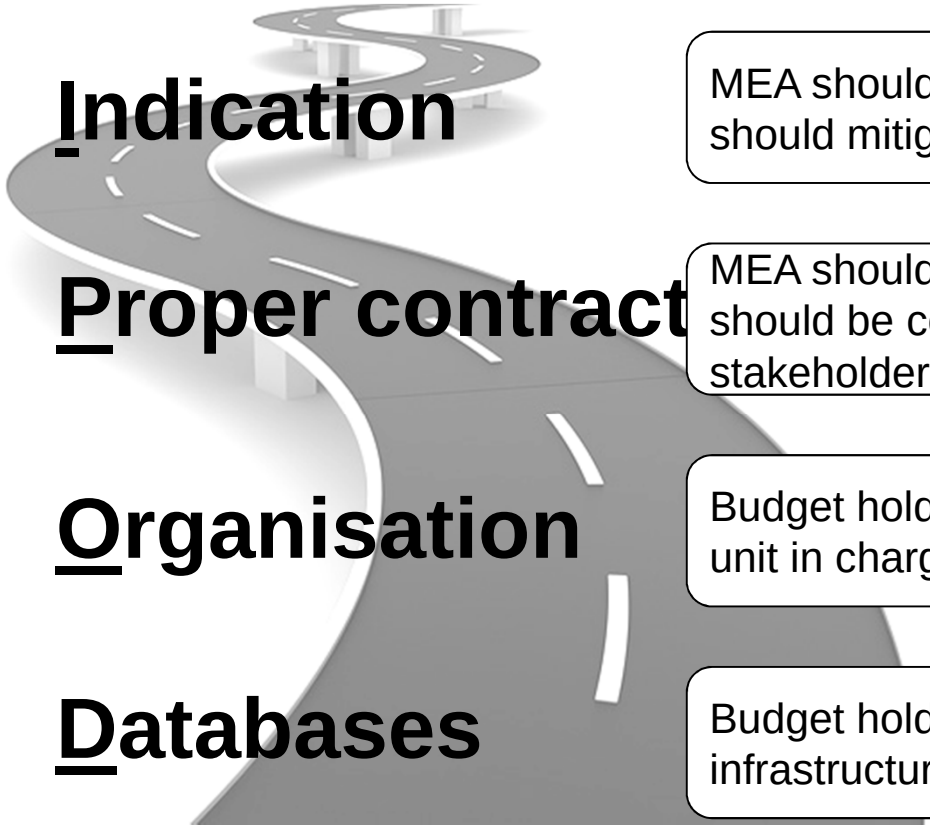
Source: own compilation

Managed entry agreements can be of several types



Source: own compilation

Managed entry agreements can only be successful if they are IPOD



Indication

MEA should match the clinical indication and should mitigate uncertainties associated with it

Proper contract

MEA should use appropriate parameters and should be consensually accepted by stakeholders

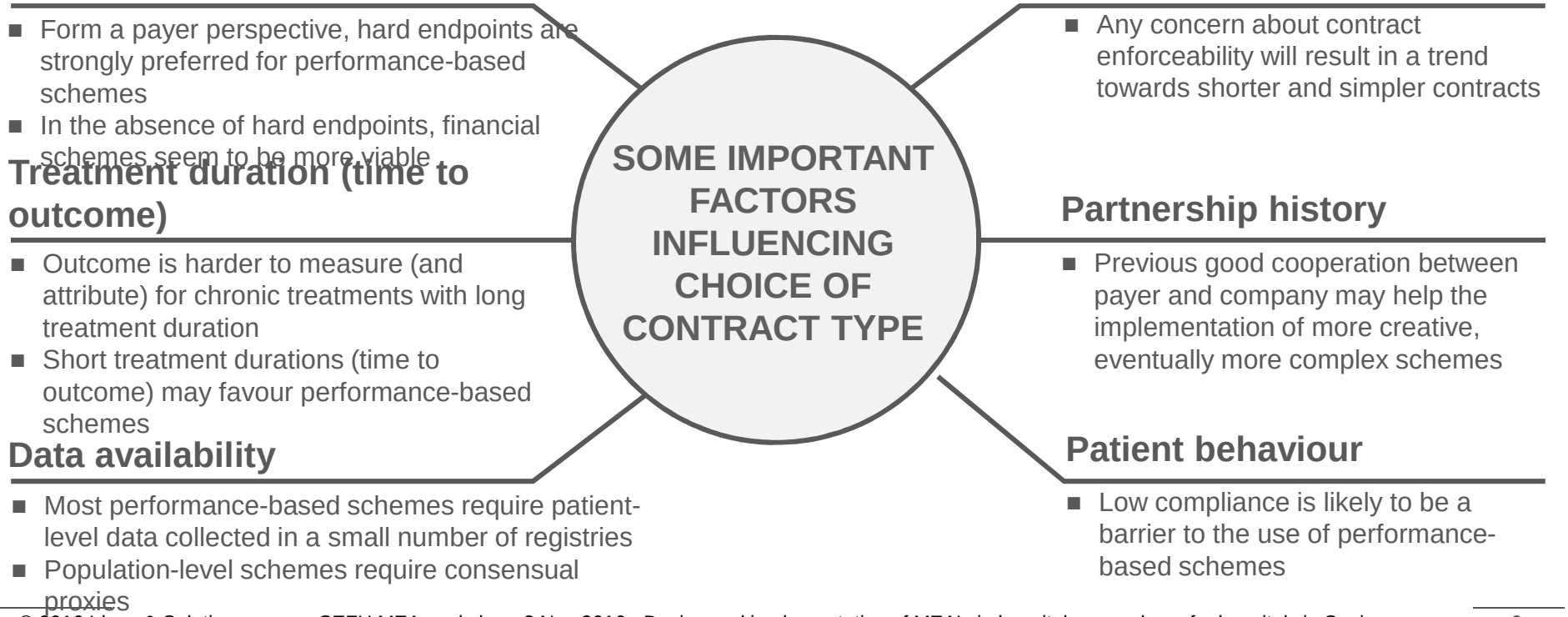
Organisation

Budget holder should have dedicated person or unit in charge of contract design and monitoring

Databases

Budget holder should have the necessary infrastructure for data collection and validation

Indication: Not all indications are suitable for all types of managed entry agreements



Measurement of clinical benefit

- Form a payer perspective, hard endpoints are strongly preferred for performance-based schemes
- In the absence of hard endpoints, financial schemes seem to be more viable

Treatment duration (time to outcome)

- Outcome is harder to measure (and attribute) for chronic treatments with long treatment duration
- Short treatment durations (time to outcome) may favour performance-based schemes

Data availability

- Most performance-based schemes require patient-level data collected in a small number of registries
- Population-level schemes require consensual proxies

Enforceability of contract

- Any concern about contract enforceability will result in a trend towards shorter and simpler contracts

Partnership history

- Previous good cooperation between payer and company may help the implementation of more creative, eventually more complex schemes

Patient behaviour

- Low compliance is likely to be a barrier to the use of performance-based schemes

Indication: Performance-based agreements serve best for high-value treatments in non-chronic, low-incidence diseases with hard endpoints

- In most jurisdictions, it is **more ‚cost-effective' to implement financial agreements** in
  - high-incidence (high-prevalence) therapy areas where patients are treated in several institutions,
  - therapy areas where measurement of real-world effectiveness requires long-term follow-up,
  - therapy areas where it is difficult to find hard endpoints.
- Despite this, **performance-based MEA's can function well for high-value therapies** where
  - incidence is low or relatively low, care is delivered in a small number of specialized institutions, whereby patient registries are possible, AND/OR
  - real-world effectiveness (outcome) can be measured with reasonable precision already in the short term.

Source: own analysis

Proper contract: payers' MEA propositions are not always fully technical – concerns and perceptions may play a role

Payer concerns	Possible MEA proposals by payer	
'I do believe in the medicine but I am in no position to take any budget risks.'	Patient number caps / Budget caps	Fixed budget schemes
'I like the medicine but I do not agree with its pricing.'	Discounts with/without budget caps	Free initiating cycles
'I don't really believe in the calculations behind the medicine yet I want to ensure patient access.'	Combination of several caps	Strict patient number cap / budget cap
'I like to experiment.'	‚Easy-to-implement' performance schemes	Coverage with evidence generation
'I am not enthusiastic about the medicine but I like fancy concepts.'	Performance-based schemes	Tiered discount agreements

Source: own compilation

Proper contract: if the parties have different expectations from a MEA, the agreement is not going to perform

Company		Budget holder (payer)
„We understand that the budget impact is too high but we can offer substantial discounts if the whole label is reimbursed.”	↯	„We are not convinced about the cost-effectiveness of this medicine.”
„We are ready to improve the cost-effectiveness of our product through a confidential discount scheme.”	↯	„We believe that this medicine only has therapeutic added benefit in a minor subpopulation of the label.”
„We have designed a particularly advantageous scheme for our new antidepressant.”	↯	„We do not believe in managed entry agreements in therapy areas where diagnostic criteria are soft.”

Contract DELAYED → **Contract NOT SIGNED** → **Contract MISINTERPRETED** → **Contract TRICKED**

Proper contract: technical parameters need to be properly designed (1)

Settlement of compensation	▪ For hospital products, compensation in cash (credit note, payback) and kind are possible. ▪ The frequency of compensation (payback) calculations needs to be determined. ▪ Also, offsetting mechanisms between periods and products can be incorporated.
Advance payments	▪ Some payers require advance payments by the pharma company in MEA's involving patient number or budget caps. This is essentially a form of commercial credit. ▪ If there is no excess at end of period, the advance payments are refunded by the payer.
Single-product and multi-product agreements	▪ MEA's can be signed for one product (INN), more products of the same pharmaceutical company or more competing products of more pharmaceutical companies. ▪ In joint MEA's, total payback by manufacturers needs to be split into individual payback obligations.
Confidentiality	▪ It must be regulated by legislation on MEA's which sections of a managed entry agreement should be publicly accessible and which are confidential. ▪ Different models exist but generally price information (in particular, discount levels) are confidential.

Proper contract: technical parameters need to be properly designed (2)

Data ownership, management and access to data	▪ Patient registries contain sensitive health information about patients which, in most legislations, only the treating physician may access. ▪ Registries need to have aggregated and de-personalized data layers which the payer and the pharma company may use for MEA purposes.
Patient / disease registry funding	▪ The funding of registries supporting MEA's is still controversial in many countries. ▪ Payers often require pharmaceutical companies to fund the necessary registries. ▪ Long-term sustainable funding can only be ensured through direct or indirect public funding.
Contract duration and renegotiation	▪ A typical MEA is signed for 2-4 years. Within this timeframe, the evolution of treatment practice and market dynamics can be predicted reasonably well. ▪ After 2-4 years, contract re-negotiations are common because of changes in the therapy landscape or in the company portfolio, price changes or tactical considerations.

Proper contract: Confidentiality of managed entry agreements

In general, MEA's typically fall under the Civil Code. As they contain sensitive commercial information, contracting parties usually insist on a certain degree of confidentiality.

1 The contract is public but price information is erased

- In this model, MEA's follow standard templates which are publicly accessible
- Price information (and in sensitive cases: supply volumes) are erased
- Example: supply contracts for high-value hospital drugs in Hungary

2 Only a list of products involved in different MEA types is public, the contracts themselves are not

- In this model, the responsible authority publishes a list of MEA's on its website
- The type of MEA for each contract is usually specified
- The contract itself is not publicly available

3 All information is confidential, nothing is publicly accessible

- In this model, no information is published on MEA's for specific products
- The existence of a MEA is not public information
- This is a non-transparent model which is not recommended

Example for confidentiality: excerpt from NHS Patient Access Scheme listing

Abiraterone (Zytiga®) for castration-resistant metastatic prostate cancer previously treated with a docetaxel-containing regimen TA259

1.1 Criteria

NICE criteria: Abiraterone in combination with prednisone or prednisolone is recommended as an option for the treatment of castration-resistant metastatic prostate cancer in adults, only if:

- their disease has progressed on or after one docetaxel-containing chemotherapy regimen, and
- the manufacturer provides abiraterone with the discount agreed in the patient access scheme

1.2 Scheme

The manufacturer has agreed a patient access scheme with the Department of Health which involves a single confidential discount being applied to the list price of abiraterone.

Source: https://www.newdevonccg.nhs.uk%2Fpermanent-link%2F%3Frid%3D100216&usg=AFQjCNEGQVB2SP-rTdP4TMLrQMhiVsRQ1A&bvm=bv.105841590,d.bGQ&cad=rja

Organization: contract design and monitoring are both essential but they are not necessarily the same payer functions

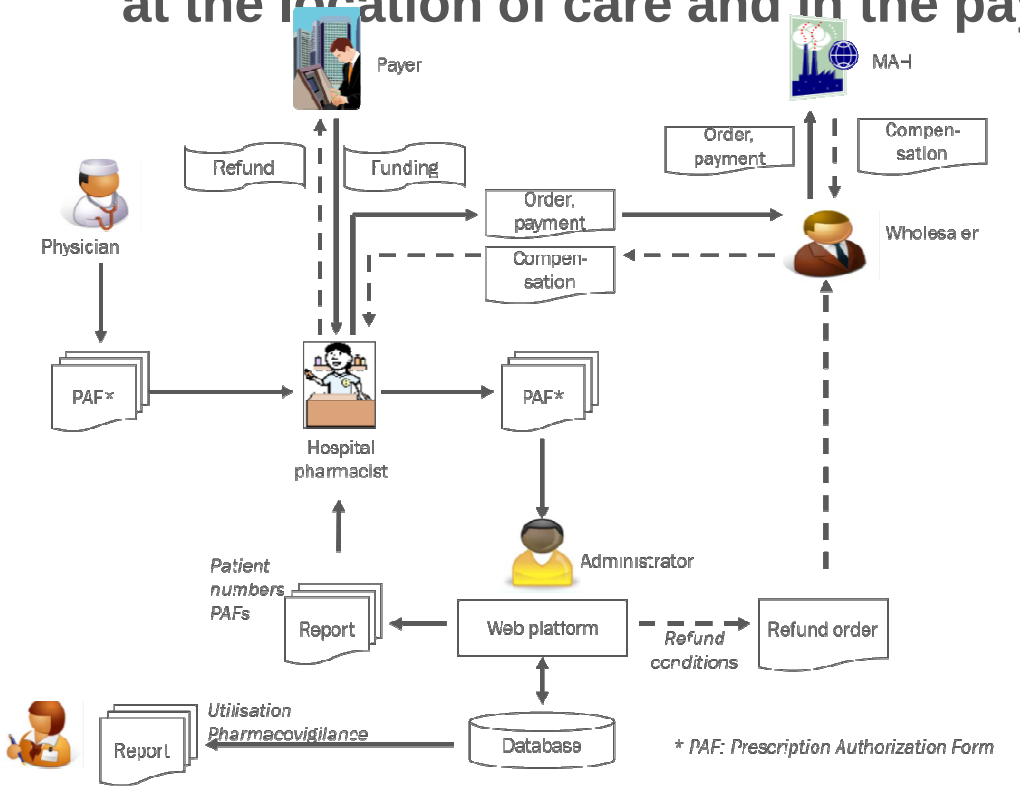
Contract design

- Strategic function linked to negotiations
- May be separate function in large organizations, tends to be leadership responsibility in smaller organizations
- Early (pre-submission) engagement may make contract design easier for both parties
- Needs experience, certain degree of creativity and legal support

Contract monitoring

- ‚Value-added' control function
- Key tasks: monitoring of contract performance → calculation and preparation of financial settlements → feedback to leadership on contract performance
- Needs analytical skills, problem-awareness and reliable information systems

Databases should be reasonably developed and highly reliable both at the location of care and in the payer organisation



- Database quality is mostly relevant for patient-level schemes
- GIGO (garbage-in garbage-out) principle applies
- Accuracy of clinical information will be the basis for financial relations
- Embedded controls are necessary
- Financing / reimbursement protocols can be built into the controls

Source: own illustration based on UK Velcade Response Scheme 2007

Some more recommendations for managed-entry agreements

- Early engagement c
  implementations
- Contacts should be
  factors are taken int
- Contract manageme
  contract benefits
- Best practice MEA's
  towards higher quali
- Performance-based
  fields of application

Sir Michael Rawlins, Chairman of UK NICE, 1999-2013, Chairman of UK MHRA, 2014-

„[MEA] schemes, generally, allow patients access to expensive new products with established effectiveness for the claimed indications, which would otherwise be cost ineffective.

[MEA's] must be simple and straightforward for the hospital's management to administer. If they include a response measure, it must be simple and reliable."

Source: Oncology Business Review, 2010/03, p16.
URL:https://obroncology.com/documents/OBR_MAR10_RS(1).pdf. Downloaded on 15 Oct 2016