ЦЭККМП | The Ministry of Health of the Russian Federation
Center for Healthcare Quality Assessment and Control

Value-based healthcare development in Russian Federation

Vitaly Omelyanovskiy

Center for Healthcare Quality Assessment and Control of the Ministry of health of Russian Federation

Values-Based Medicine - *medical practice that aims at maximizing value, specifically desirable or positive value in every step of a patient's medical management*

Ten principles of values-based medicine, http://www.wpanet.org/uploads/Sections/Philosopy_and_Humanities/ten-principles-of-value-based-medicine.pdf

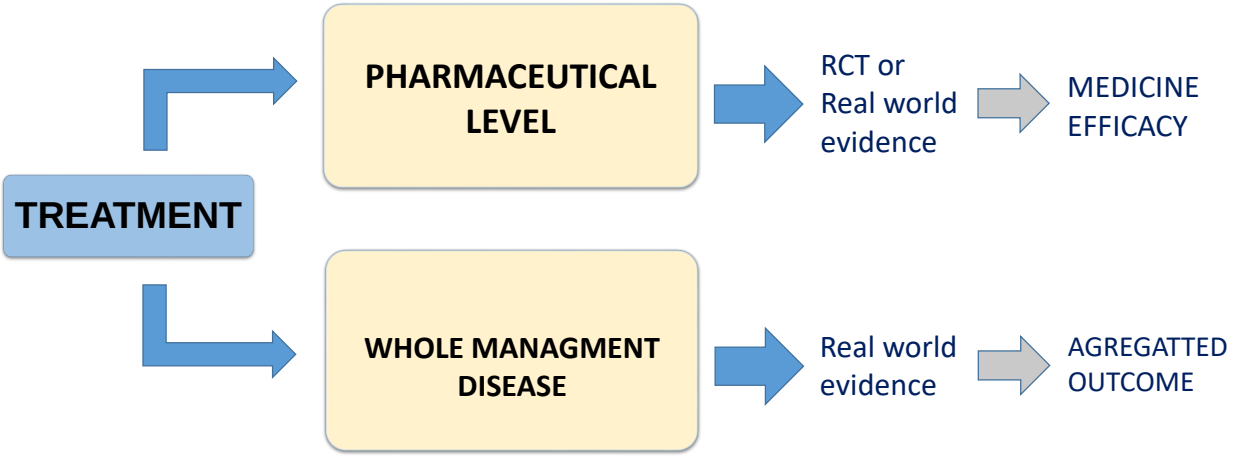
FUTURE OF HEALTHCARE: A PARADIGM SHIFT

Traditional Health Care → **Value-based health care**

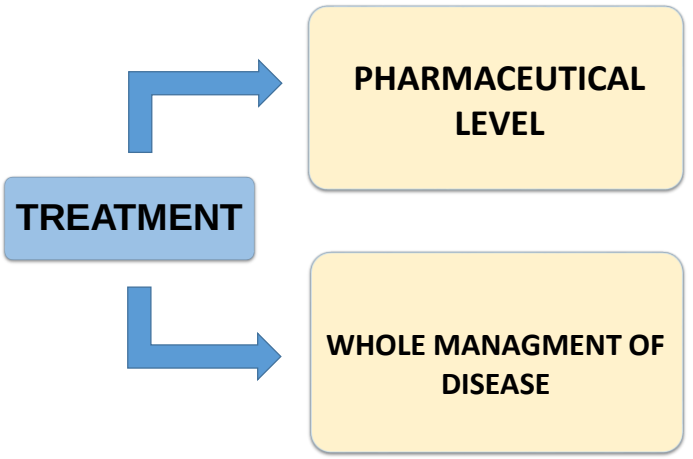
1. Process and **volume control** in healthcare;
2. Monitoring of outcomes of **low importance for patients**;
3. Costs and outcomes monitoring at the **population** level.

1. Monitoring of the **final result**;
2. Monitoring of standard **results of high importance for patients**;
3. Costs and outcomes monitoring at the **individual** level.

ASSESSING THE EFFICACY OF THE NEW TREATMENT OPTION



VALUES-BASED MEDICINE



Values-Based Pricing is a strategy of setting prices primarily based on a consumer's **perceived value** of a product or service.

VBP or/and MEA (RSA)

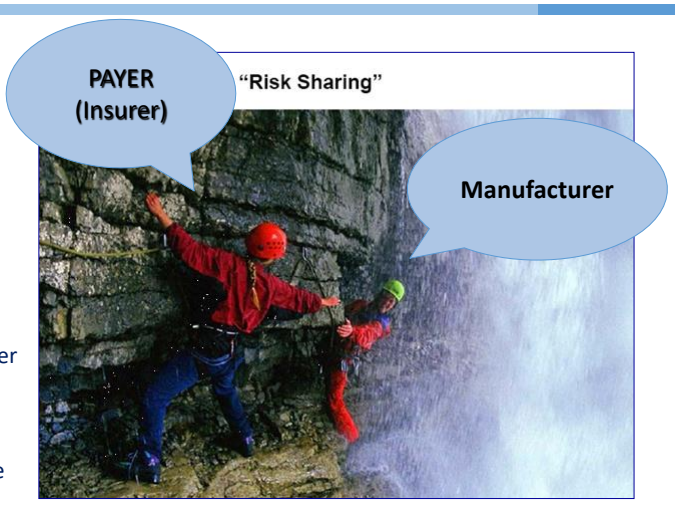
Managed entry agreements (MEAs) are a set of instruments to facilitate access to new medicines.

P4P approach

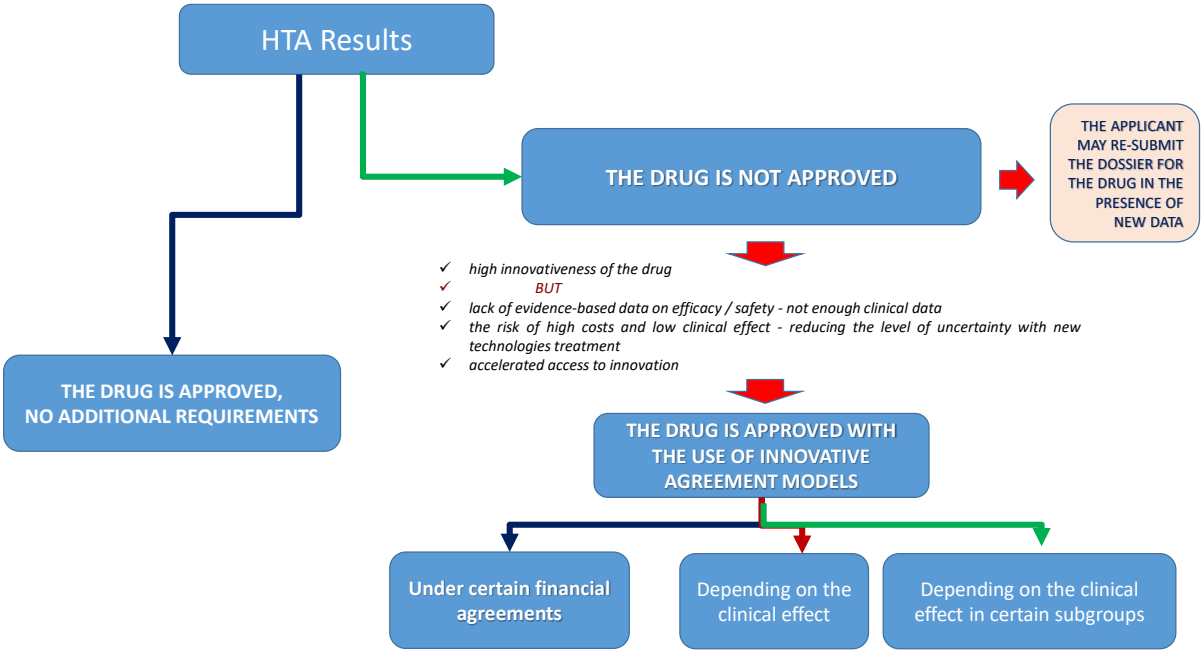
P4P is a **payment** model that offers financial incentives to physicians, hospitals, medical groups, and other healthcare providers for meeting certain **performance** measures.

PHARMACEUTICAL LEVEL

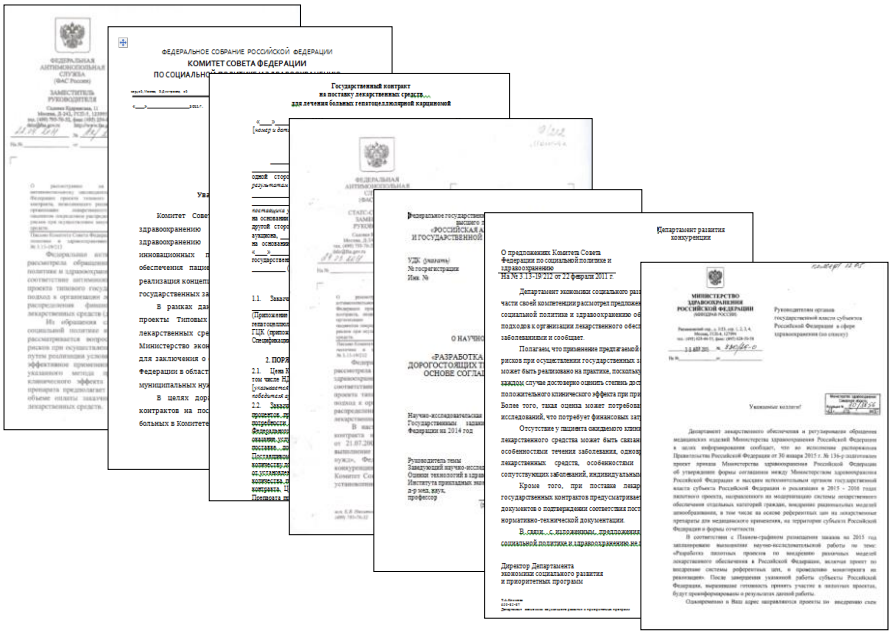
FACILITATING ACCESS TO NEW MEDICINE AND INNOVATIONS



Risk-sharing agreement*(RSA)* — arrangement between a payer and a pharmaceutical or diagnostic manufacturer where the price level or nature of reimbursement is related to the actual performance of the product in the research or 'real world' environment.
Aims to ensure better budgetary control and a lower **risk** of spending on medicinal products without full evidence of clinical benefit



2010 - 2015



GOVERNMENT ORDER

PILOT PROJECT ON THE DRUG SUPPLY UNDER INNOVATIVE CONTRACT MODELS (RISK-SHARING AGREEMENTS)

ПРОТОКОЛ

совещания у Первого заместителя Председателя Правительства Российской Федерации И.И.ШУВАЛОВА

Москва

от 21 апреля 2016 г. № ИШ-П12-26пр

Присутствовали:

Министр здравоохранения Российской Федерации	- В.И.Скворцова
заместитель Министра экономического развития Российской Федерации	- Е.И.Елин
заместитель Министра промышленности и торговли Российской Федерации	- С.А.Цыб
руководитель ФАС России	- И.Ю.Артемьев
ответственные работники федеральных органов исполнительной власти, Аппарата Правительства Российской Федерации и заинтересованных организаций	- В.И.Власов, В.Л.Дорофеев, И.И.Дорохова, О.Н.Колотилова, Н.Н.Лебедева, Е.А.Максимкина, Ю.В.Мочалин, Е.Б.Погодина, С.Н.Решетников, М.А.Романова, Ю.Г.Сиренко, И.В.Федотов

О разработке новых механизмов закупок лекарственных препаратов для обеспечения государственных и муниципальных нужд

(Максимкина, Погодина, Дорохова, Артемьев, Цыб, Елин, Скворцова, Шувалов)

1. Принять к сведению информацию Минздрава России (В.И.Скворцова), Минэкономразвития России (Е.И.Елин), Минпромторга России (С.А.Цыб) и ФАС России (И.Ю.Артемьев) по данному вопросу.

2

2. Минздраву России (В.И.Скворцовой), Минэкономразвития России (А.В.Улюкаеву), Минпромторгу России (Д.В.Мантурову), ФАС России (И.Ю.Артемьеву) совместно с заинтересованными федеральными органами исполнительной власти с учетом состоявшегося обсуждения проработать, принимая во внимание международный опыт, предложения:

о поставке лекарственных препаратов по инновационным моделям договоров, предусматривающих предоставление скидок на лекарственный препарат при высоких объемах его закупки, а также определение объема платежей за лекарственный препарат с учетом результатов лечения;

о заключении соглашений об обязательствах производителя безвозмездно передавать часть лекарственных препаратов заказчикам при выполнении ими определенных (отлагательных) условий.

Согласованные предложения представить в Правительство Российской Федерации до 16 мая 2016 г.

3. Минздраву России (В.И.Скворцовой), Минэкономразвития России (А.В.Улюкаеву), Минпромторгу России (Д.В.Мантурову), ФАС России (И.Ю.Артемьеву) совместно с заинтересованными федеральными органами исполнительной власти проработать вопрос реализации пилотного проекта в субъектах Российской Федерации по внедрению механизмов закупок, указанных в пункте 2 настоящего протокола, и о результатах доложить в Правительство Российской Федерации до 16 мая 2016 г.

Первый заместитель Председателя Правительства Российской Федерации И.Шувалов

RISK-SHARING AGREEMENTS

- EXPENSIVE TECHNOLOGIES
- PRESERVING THE LEVEL OF DRUG PRICES

IN THE WORLD

1. Faster access to innovation
2. Technologies that have not passed the HTA- use of agreements in the absence of evidence-based data on the effectiveness / safety of new technologies
3. Reduced level of uncertainty in the treatment of new technologies
4. Low level of project administration

RUSSIAN FEDERATON

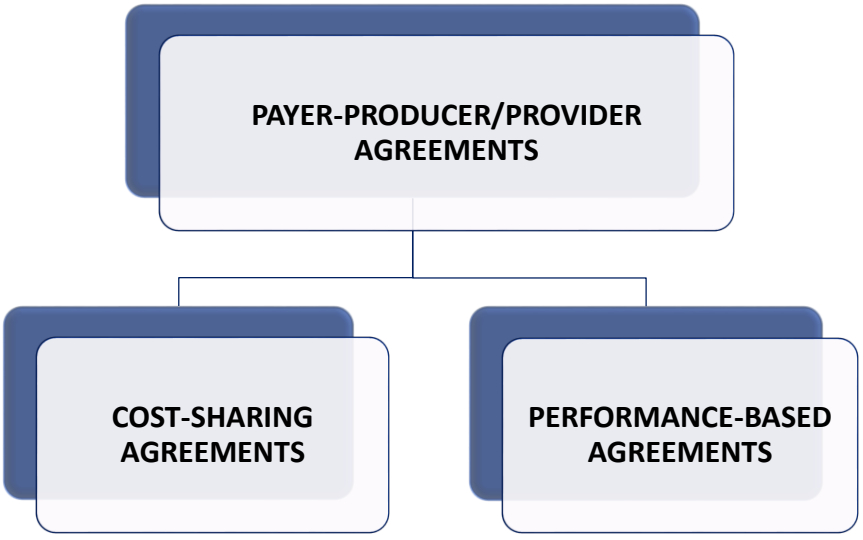
1. Drugs Only
2. Mostly Drugs Included in the VED list
3. Mostly regional level
4. The main motivation is to increase procurement of drugs already included in the lists
5. Low interest of payers

25 APPLICATIONS WERE SUBMITTED FROM 11 PHARMACEUTICAL COMPANIES FOR 15 INDICATIONS

№	Submitted Indications
1	Hepatic cell carcinoma
2	Phenylketonuria
3	Rheumatoid arthritis
4	Chronic hepatitis C
5	Breast cancer
6	Multiple sclerosis
7	Prostate cancer
8	Ankylosing Spondylitis

№	Submitted Indications
9	Crohn's disease
10	Ulcerative colitis
11	Myelofibrosis, true polycythemia
12	Chronic myeloid leukemia
13	Juvenile idiopathic polyarthritis
14	Nonvalvular atrial fibrillation
15	Thromboprophylaxis after arthroplasty

TYPES OF AGREEMENTS INCLUDED IN THE PROJECT



«Центр экспертизы и контроля качества медицинской помощи»
Министерства здравоохранения Российской Федерации
(ФГБУ «ЦЭККМП» Минздрава России»)

Проект

МЕТОДИЧЕСКИЕ РЕКОМЕНДАЦИИ ПО ПРОВЕДЕНИЮ КОМПЛЕКСНОЙ ОЦЕНКИ ЛЕКАРСТВЕННОГО ПРЕПАРАТА ДЛЯ ПРИНЯТИЯ РЕШЕНИЙ О ВОЗМОЖНОСТИ ЕГО ВКЛЮЧЕНИЯ В ПИЛОТНЫЙ ПРОЕКТ ПО ВНЕДРЕНИЮ В СУБЪЕКТАХ РФ МЕХАНИЗМОВ ЗАКУПОК ЛЕКАРСТВЕННЫХ ПРЕПАРАТОВ ПО ИННОВАЦИОННЫМ МОДЕЛЯМ ДОГОВОРОВ

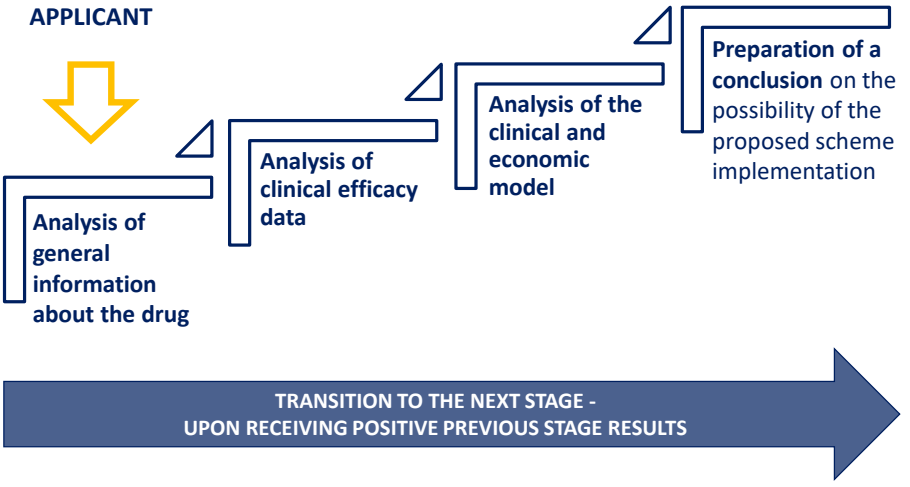
- **GUIDELINES FOR DRUG COMPREHENSIVE ASSESSMENT**

FOR MAKING DECISIONS ABOUT THE POSSIBILITY OF ITS INCLUSION IN THE PROJECT

Москва 2017 г.

www.rosmedex.ru

STAGES OF DRUG COMPREHENSIVE ASSESSMENT WITHIN THE PILOT PROJECT



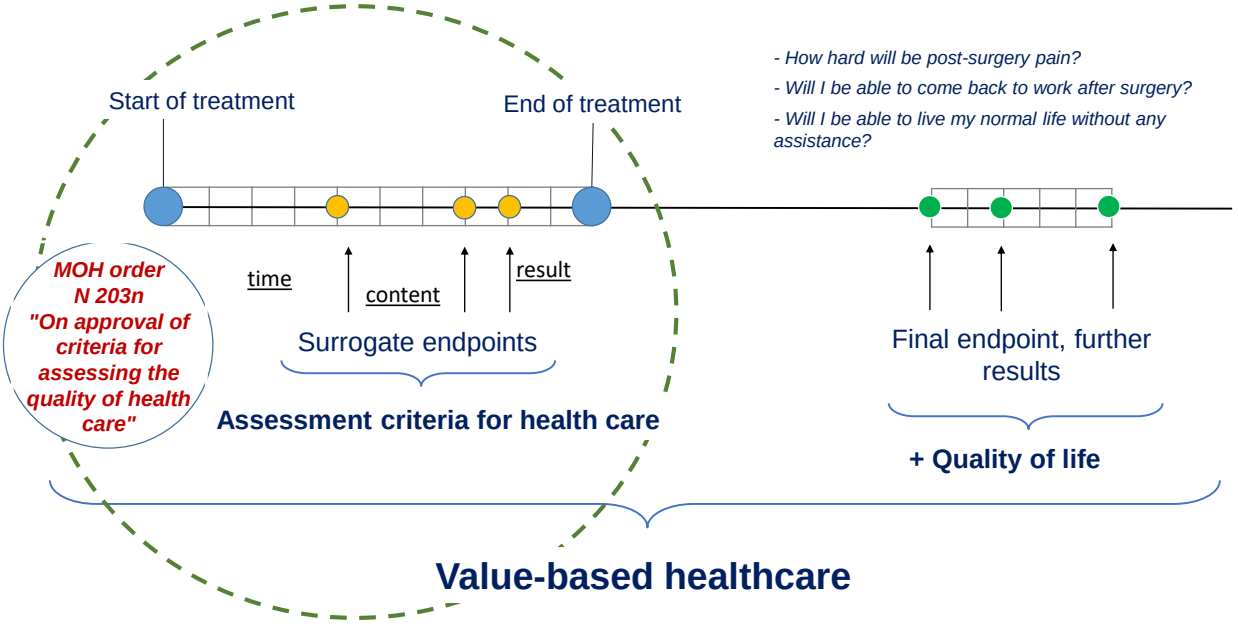
PILOT PROJECT IMPLEMENTATION CONDITIONS ACCORDING TO THE FEDERAL ANTIMONOPOLY SERVICE

- Only on-patent and Innovatine drugs
- For drugs not included in the VED list
- The need for the drug use is due to the inability to use other drugs
- Patients must be insured
- The pilot project should be carried out according to uniform rules
- 100% compensation of budgetary expenses by the supplier in case of a negative result of the pilot project
- The maximum selling price is agreed upon and calculated in accordance with the methodology of calculating selling prices for drugs included in the VED list
- **Project implementation in private clinics**

WHOLE MANADGMENT
DISEASE LEVEL

17

SURROGATE AND FINAL ENDPOINTS



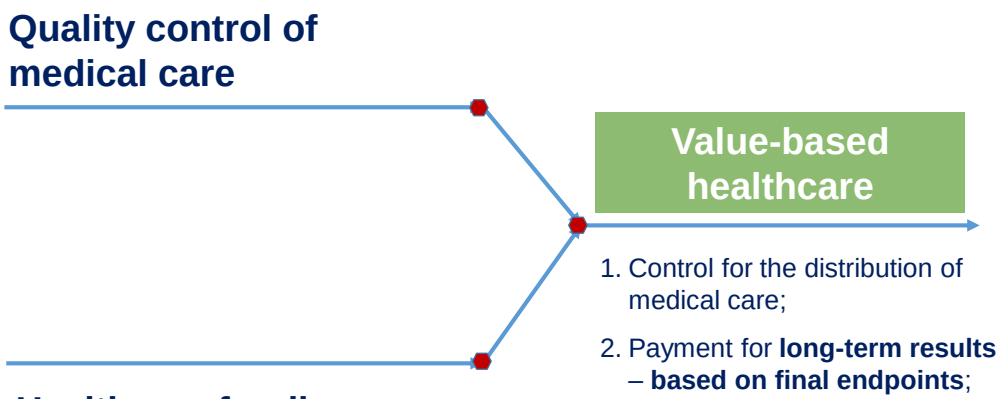
Russian specifics

- **DRG system**, that can not affect the quality
- **Quality criteria** have been implemented since the last year
  - Only **inpatient**
  - Measurable **outcomes** turn out to be **not important for patients**
- **Pilots** will be able to **evaluate** the **possibility of the implementation of final outcomes important for patients**

On the other hand

- Hospitals compete for state-provided amounts of medical care
- VBHC could be the transparent approach of distribution of medical care

FROM RESULT TO FUNDING



1. Control for the distribution of medical care;
2. Payment for **long-term results – based on final endpoints**;
3. "Bonus for quality" = a premium for good results.

FUTURE OF HEALTHCARE: A PARADIGM SHIFT

Traditional Health Care → **Value-based health care**

1. Process and **volume control** in healthcare;
2. Monitoring of outcomes of **low importance for patients**;
3. Costs and outcomes monitoring at the **population** level.

1. Monitoring of the **final result**;
2. Monitoring of standard **results of high importance for patients**;
3. Costs and outcomes monitoring at the **individual** level;
4. Payment for the result or **recalculation of state-provided amounts of medical care** depending on the result.

VBHC IMPLEMENTATION PLAN IN RUSSIAN

Current projects

1. Cataract (2019)

Future projects

2. Inflammatory bowel disease (2020)
3. Diabetes (2020)
4. Coronary artery disease (2020)

CATARACT

- **S. Fyodorov Eye microsurgery federal state institution** of the Ministry of Health of the Russian Federation:
  - **Moscow** branch: **270**
  - **Kaluga** branch: **50**
  - **Tambov** branch: **548**
  - **Orenburg** branch: **509**

  } **1 377**
- **Private** hospital: **350**

} **1 727**

Patients passed: 1 727

Scheduled: 2 500

ЦЭККМП | The Ministry of Health of the Russian Federation
Center for Healthcare Quality Assessment and Control

23

CONCLUSION

- Value-based health care is a **new trend** in the **evaluation** of healthcare **results** and its **funding**.
- **Risk-sharing**, as a special case of value-based health care, promotes **improvements** in **efficiency** of **budget allocation** and **spending**.
- The new paradigm of health care – **value-based health care**, **requires** a reset of the entire system of **quality control** for healthcare and its **informatization**.

Thank you!