

Achieving a healthy society of longevity

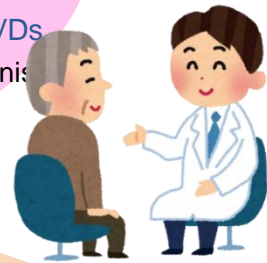
Improving public convenience

Industrial development and economic revitalization

Fiscal consolidation of the health insurance system

1. Addressing diversified public needs

- ✓ Creating a new mechanism for incorporating treatments not covered by medical insurance
- Launch a new "Patient-Filed Treatment (tentative)" mechanism
- ✓ Improving the pricing system for innovative pharmaceuticals
- Reflect greater recognition of innovativeness to drug pricing and improve price predictability.
- ✓ Prompt establishment of the structure for switching Medical IVDs into OTC IVDs
- Urgently build the switching structure, provide information and develop a mechanism for recommending medical consultation



ICT use

2. Building an efficient and high-quality healthcare system

- ✓ Building a healthcare system for optimum regional medical services
- Establish a Primary Care system and coordinate healthcare programs with long-term care programs.
- ✓ Enhancing community-based medical care and long-term care
- Clarify the requirements for clinics that primarily provide in-home care.
- ✓ Developing the "specified nursing actions"
- Expand the scope of nurses' activities permitted without doctor's presence.



3. Streamlining services and strengthening governance

- ✓ Strengthening the business management of long-term care and childcare businesses
- Obligate social welfare service corporations to conduct information disclosure and social contribution activities.
- ✓ Developing an environment for enhancing / reinforcing health insurance providers' functions
- Support the use of health insurance claim data and introduce the advance-check system by health insurance providers.
- ✓ Strengthening the business foundation of medical institutes
- Promote the use of human resources with extensive management experiences, and build a legal compliance system.



Expanding the Mixed Billing System

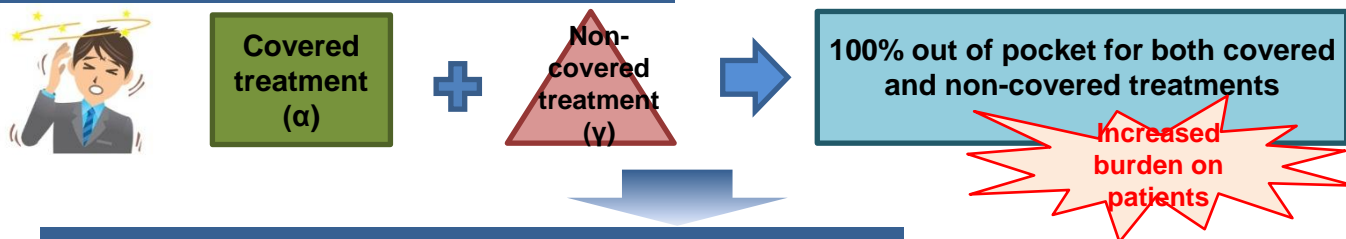
Current status

- When a patient receives treatment covered by public health insurance in combination with treatment not covered by the insurance, the patient must pay the full cost of both of the treatments unless the combined treatment is authorized under the so-called Mixed Billing system. The current Mixed Billing system has the following issues:
 - It takes 6 – 7 months from the time of application for authorization.
 - For each of the medical technologies, only about ten medical institutions cater to the system on average.
 - Patients must meet certain criteria for authorization.

When the Mixed Billing system is applied



When the Mixed Billing system is not applied



Substantial expansion of the Mixed Billing system

Mixed Billing system

Assessment treatments
(7 types)

Elective treatments
(10 types)



Patient-Filed Treatment

[Features of "Patient-Filed Treatment (tentative)"]

- Initiated from **patients' applications**
- Treatment may be started **in 2 weeks in principle** for treatments with precedent, and **6 weeks in principle** for treatments without precedent.
- Participating medical institutions are added constantly to enable flexible use of the program, allowing patients to receive treatments at **nearby medical institutions**.
- The government commissions an expert panel to confirm **safety and efficacy**.
- A **protocol toward extending insurance coverage to such treatments** is drawn up, while serious adverse events are reported to the government.
- When a **patient who does not meet criteria** files an application, the government consults a **panel of experts before authorizing the treatment**.

Regulatory reform content

- Establish the Patient-Filed Treatment (tentative)" system as a new mechanism within the Mixed Billing system through law amendment.

Anticipated effect

- The reform will allow the use of pharmaceuticals not approved in Japan or the off-label use of pharmaceuticals swiftly under the Mixed Billing system, expanding the treatment options of patients of difficult diseases who file an application.

Consolidating Business Management of Long-term Care and Childcare Businesses

Current status

Main issues highlighted about social welfare corporations

- Insufficient disclosure of information including financial statements and director remunerations
- Expected to play a major role as a provider of local social welfare services, but failing to meet the expectations while building up excessive retained earnings

1 Reinforcement of business management

Current status

Information disclosure

Disclosed upon request from users

Retained earnings

Not utilized systematically

Review by a third-party organization

Audit by local municipal authority only, and no third-party review

After the reform

Disclosure of financial statements and directors' remunerations (obligation)

Systematic appropriation for investments and improvement of workers' conditions

Use of third-party review to improve user services

2 Equivalent conditions of competition

Social contribution

Voluntary (tax exempt)

Obligation

Regulatory reform content

- Promoting the disclosure of social welfare corporations' financial statements, directors' remunerations, etc. for better management transparency, so as to provide a sense of security to welfare service users
- Obligating social welfare service corporations to engage in social contribution activities to put them on equal footing with business enterprises and NPOs

Anticipated effect

- The reform will lead to efficient and appropriate delivery of welfare services that meet the needs of users, thereby boosting the level of convenience and satisfaction for the general public.

Appropriately recognizing innovation in calculating the pricing for pharmaceuticals / medical devices, and improving price predictability

Current status

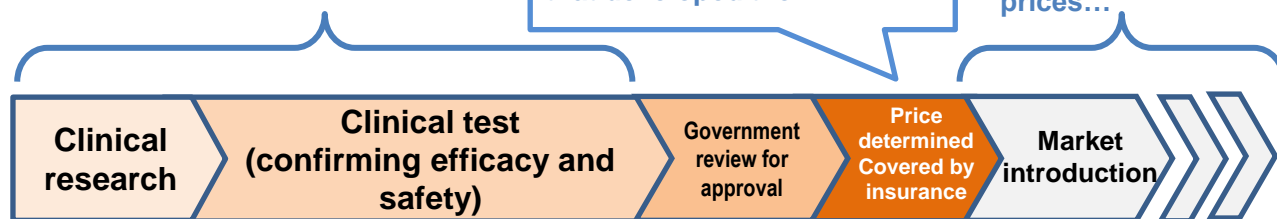
- The level of innovation is sometimes not fully recognized when determining the prices of pharmaceuticals and medical devices.
- The complex rules about the government pricing of pharmaceuticals and medical devices make it difficult for companies to predict the final pricing of their own products, posing a major business risk.

Path to pharmaceuticals' market introduction

[Investment of development expenses]
Requiring tens of billions of yen in investment

The prices of pharmaceuticals and medical devices are set behind closed doors by pricing counsel, etc. and do not necessarily reflect the prices anticipated by the companies that developed them.

[Cost recovery]
It might become impossible to recover investment costs depending on the final prices...



[Reform plan]
○Developing / clarifying a mechanism to allow companies to consult the MHLW about pricing outlook as appropriate

[Reform plan]
○Appropriately assessing innovation used in pharmaceuticals and medical devices, and reflecting it to prices
○Exploring clear assessment criteria

Regulatory reform content

In calculating the prices of pharmaceuticals and medical devices:

- Appropriately assess the level of innovation involved, e.g. by setting performance indicators on the improvement of patients' QoL
- Develop and clarify a mechanism to allow companies to consult the MHLW about pricing rules and outlook as appropriate
- Explore clear criteria on assessing innovation

Anticipated effect

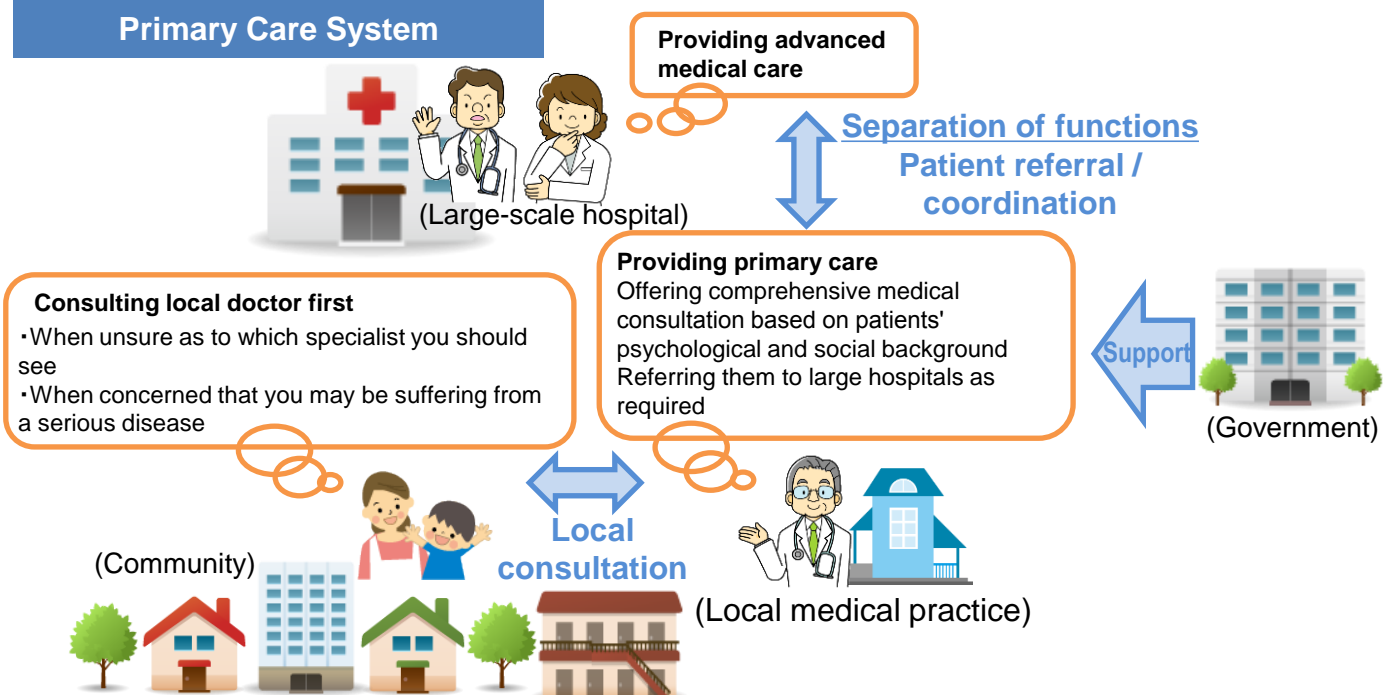
- The reform will appropriately reflect innovation in pharmaceuticals and medical devices to their pricing, thereby promoting innovation.
- The reform will boost the price predictability of pharmaceuticals and medical devices, which reduces risks associated with the development of such products.

Establishing the Primary Care System

Current status

- Japan does not have enough "Primary Care" specialists, who take a comprehensive diagnostic approach based on patients' physical / psychological state, social background, etc.
- Primary care is provided by large-scale hospitals, which should be focusing on advanced medical care. This as a result hinders large-scale hospitals from specializing in advanced medical care.

Primary Care System



Regulatory reform content

For medical practitioners to specialize in primary care:

- Exploring the development of systems for providing specialization training and updating qualifications
- Reviewing the medical advertising system
- Examining measures for developing the system for providing primary care, e.g. promoting the initiative to have multiple doctors coordinate to enable round-the-clock care

Anticipated effect

- The reform will have educated and trained local doctors handle primary care, so that local residents can develop trusting relationships with the doctors and gain a sense of security.
- The reform will allow large hospitals to focus on advanced medical care, enhancing the delivery of medical services.

Enhancing Community-based Care and Long-term Care

Current status

- The screening criteria for opening a clinic differ between individual Regional Bureaus of Health and Welfare and Local Public Health, providing constraints on those trying to open a clinic primarily providing in-home care.

Clarifying the criteria for opening a clinic primarily offering in-home care

Current status

Unclear interpretation of laws and regulations, causing variations in screening criteria from offices to offices

Prefecture A

Regional Bureau of Health and Welfare / Local Public Health

Prefecture B

Regional Bureau of Health and Welfare / Local Public Health

Variations in screening criteria

- Requiring longer outpatient consultation hours
- Requiring an X-ray room, etc.
- Accepting shorter outpatient consultation hours
- Not requiring an X-ray room, etc.

Medical institute

After the review

Clarifying the criteria for opening a clinic

Prefecture A

Regional Bureau of Health and Welfare / Local Public Health

Prefecture B

Regional Bureau of Health and Welfare / Local Public Health

Unified interpretation of laws and regulations

Standardized screening criteria among Regional Bureaus of Health and Welfare and Local Public Health

Medical institute

Regulatory reform content

- Clearly defining the criteria for opening a clinic, e.g. not necessarily requiring an X-ray room
- Exploring ways of having a clinic, primarily providing in-home care, receiving outpatients

Anticipated effect

- The reform will eliminate regional disparity in the screening criteria for opening a clinic, making it easier to plan the establishment of new clinics.

Prompt Establishment of the Structure for Switching Medical IVDs into OTC IVDs

Current status

- The use of over the counter (OTC) In-Vitro Diagnostics (IVDs) is allowed only for three testing items, with no new item added for more than 20 years (since 1991).
- There is no structure for switching Medical IVDs into OTC IVDs.

1 System for switching Medical IVDs into OTC IVDs

Specifying “testing items” for OTC IVDs <MHLW>

- Pre-defining product quality criteria including reference value range



2 Providing information to purchasers

<Matters to be described in package insert>

- Measurement results as a guide for seeking medical consultation
- Issues to be noted
- Potential of producing incorrect results
- Recommendation for receiving regular health checkup

<Explanation to be offered at the time of sales>

- Providing information according to the classification of OTC drugs
- Recommending follow-up and medical consultation based on test results as required

Regulatory reform content

- Building a system for switching Medical IVDs into OTC IVDs
- Presenting standard period for approval review and clarifying advance consultation system
- Developing the structure for providing information (instructions, explanation at sales) on the correct use of reagents and recommending medical consultation

Anticipated effect

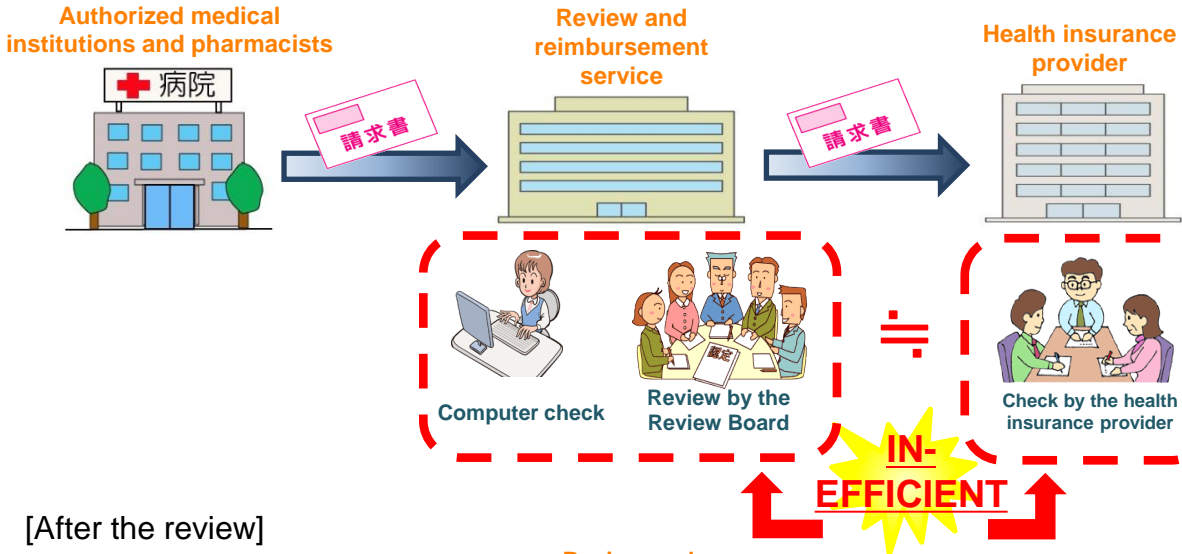
- The reform promotes self care, thereby contributing to the maintenance and enhancement of public health.

Introducing a Mechanism that Enables Health Insurance Providers to Inspect All Insurance Claim Data

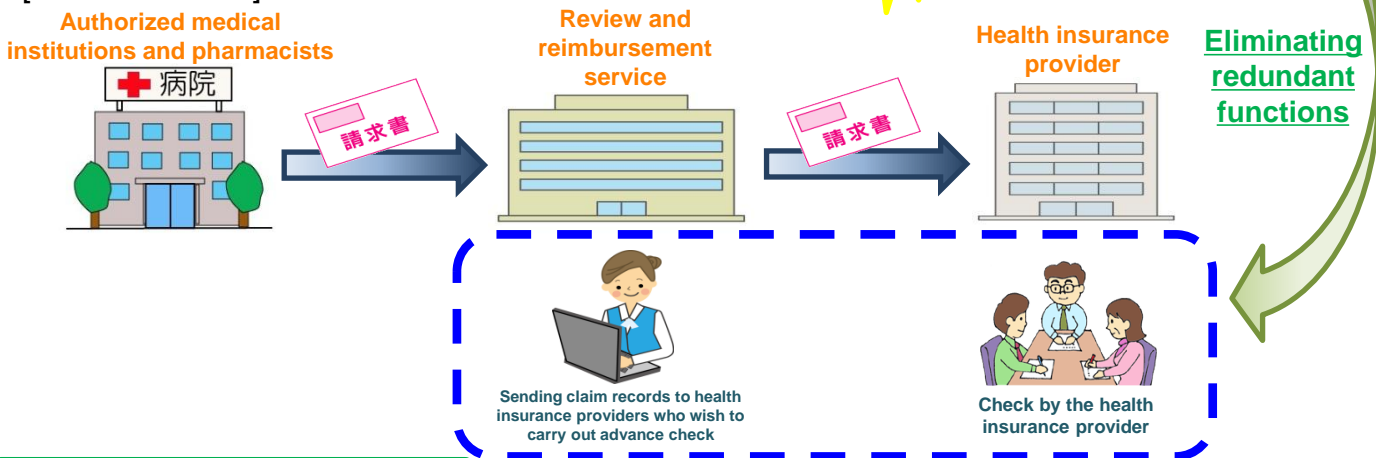
Current status

The current system is not efficient, as health insurance claims are reviewed by claim review and reimbursement services first, and then by health insurance providers again.

[Current status]



[After the review]



Regulatory reform content

- Allowing health insurance providers to inspect all insurance claim data in advance before review by the review and reimbursement services, if they wish to do so

Anticipated effect

- The reform will eliminate redundant checks on health insurance claim data to streamline the claim review and reimbursement duties.
- The reform will reduce the number of review requests to the review and reimbursement services, saving on review commissions.

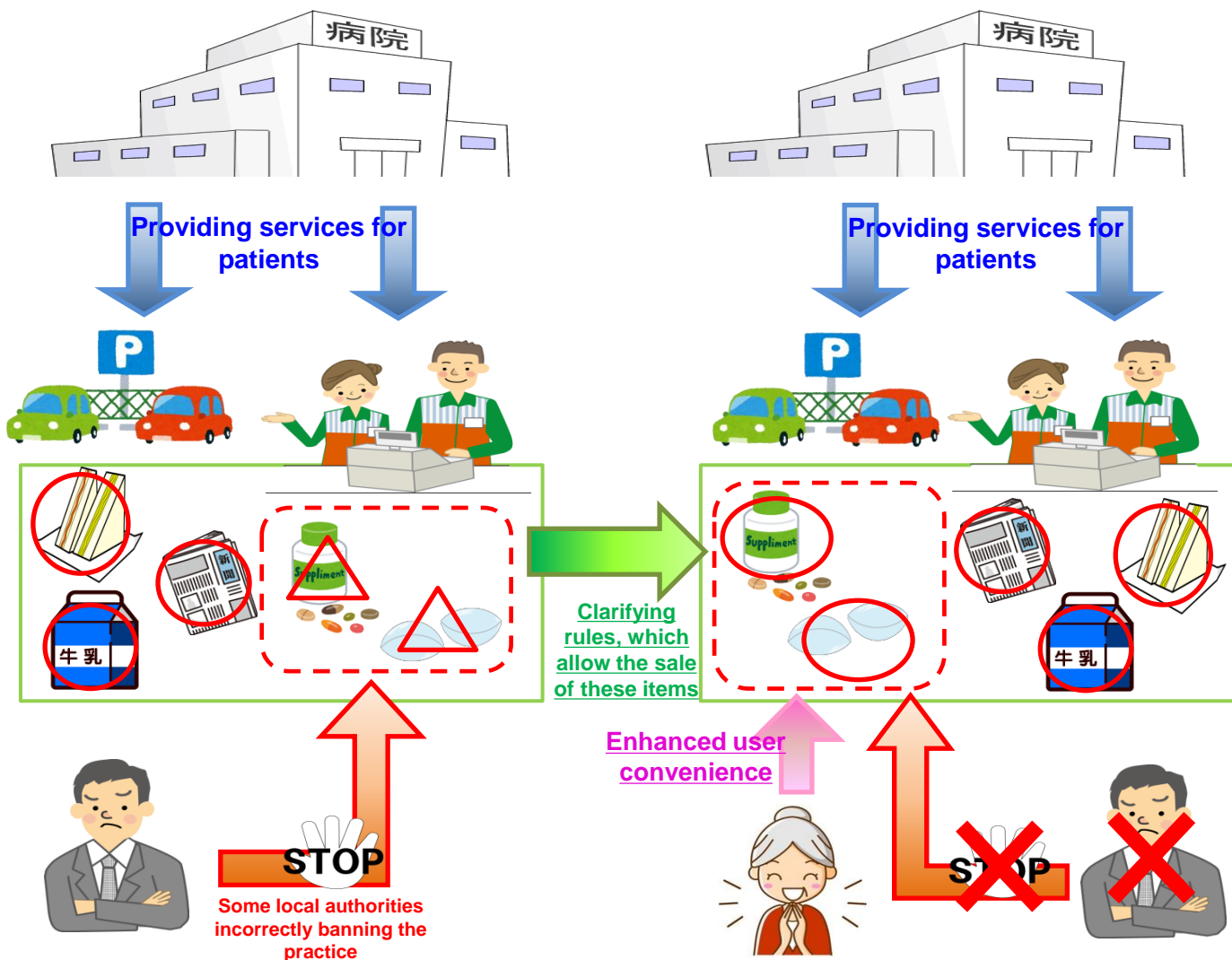
Clarifying Medical Institutes' Scope of Business Operations

Current status

- While medical institutes can offer services such as food sales, some local authorities incorrectly prevent them from running such services.

[Current status]

[After the review]



Regulatory reform content

- Clarifying that medical institutes are allowed to sell medical devices (e.g. contact lenses) and dietary supplements to patients, and circulating the information

Anticipated effect

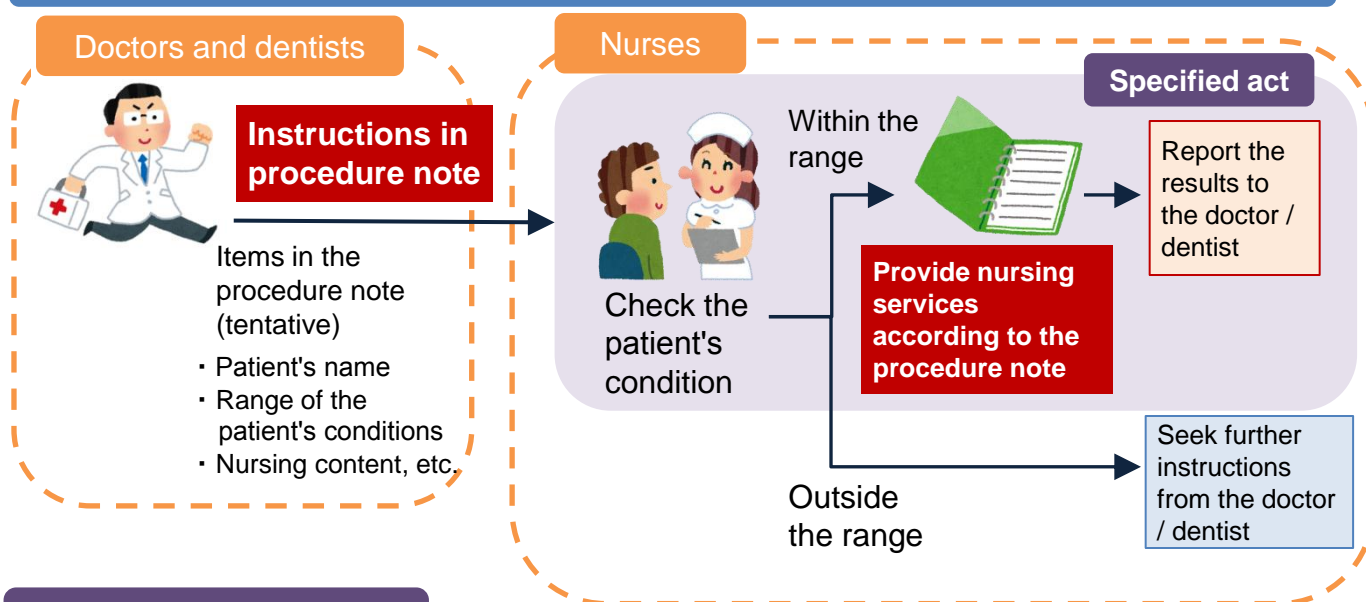
- The reform will allow medical institutes to offer services that meet patients' needs, thereby enhancing user convenience.

Developing "Specified Nursing Actions"

Current status

- Further spread of in-home care is expected to increase situations in which nurses must provide nursing service unaccompanied by doctors.
- There should be a mechanism in which nurses may make a judgment on patients' conditions and perform medical services based on instructions prepared by doctors in advance.

<New system> Overview of "specified nursing actions" (since October 2015)



Specified Act training

- **Performing specified actions requires "practical capacity to understand, think and judge" and "advanced and specialized knowledge and skills".**

→ Obligate nurses to complete "specified actions training". The training program is to be adopted by MHLW, based on the Medical Ethics Council.

Content of specified acts (draft)

- **41 acts according to the current MHLW draft (e.g. "determining the level of dehydration and correcting the condition with transfusion")**

→ To be decided after deliberations at the Medical Ethics Council

Regulatory reform content

- Ensuring that the training on specified acts boost nurses' ability to judge patients' conditions
- Ensuring that the items in the procedure note is not excessively detailed
- Selecting and circulating actions that are not previously considered to be specified acts but can be performed by nurses

Anticipated effect

- The reform is expected to help nurses actively support doctors, while maintaining the quality of medical care at patients' home or at long-term care facilities that do not have any doctor permanently stationed.