Health and Medical Field (Objectives and perspectives for regulatory reform)

Achieving a healthy society of longevity

**Improving public convenience**
- 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

**Industrial development and economic revitalization**
- 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.

**Fiscal consolidation of the health insurance system**
- 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.

1. Addressing diversified public needs
- ICT use

2. Building an efficient and high-quality healthcare system

3. Streamlining services and strengthening governance
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

- Covered treatment \((\alpha)\) + Non-covered treatment \((\beta)\) → Insurance coverage for the covered treatment (70%) + Out-of-pocket cost for the covered treatment (30%) + Non-covered treatment 100% out of pocket

When the Mixed Billing system is not applied

- Covered treatment \((\alpha)\) + Non-covered treatment \((\gamma)\) → 100% out of pocket for both covered and non-covered treatments

Substantial expansion of the Mixed Billing system

[Features of "PatientFiled 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 PatientFiled 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.
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

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

Clinical research
Clinical test (confirming efficacy and safety)
Government review for approval
Price determined Covered by insurance
Market introduction

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

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.
Support
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

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.

Consulting local doctor first
- When unsure as to which specialist you should see
- When concerned that you may be suffering from a serious disease

Separation of functions
Patient referral / coordination

Providing primary care
Offering comprehensive medical consultation based on patients' psychological and social background
Referring them to large hospitals as required

Providing advanced medical care

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.
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.

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

**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.

**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

**Current status**
- Unclear interpretation of laws and regulations, causing variations in screening criteria from offices to offices

**Variations in screening criteria**
- Prefecture A: Regional Bureau of Health and Welfare / Local Public Health
  - Not requiring an X-ray room, etc.
- Prefecture B: Regional Bureau of Health and Welfare / Local Public Health
  - Requiring longer outpatient consultation hours
  - Requiring an X-ray room, etc.

**After the review**
- 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
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

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

Marketing Authorization Holders

Notice

Apply

Notice

Pharmaceutical and Medical Devices Agency

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.

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.

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

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

**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.
Ensuring that the training on specified acts boosts nurses' ability to judge patients' conditions

Ensuring that the items in the procedure note are not excessively detailed

Selecting and circulating actions that are not previously considered to be specified acts but can be performed by nurses

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.

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.

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

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.