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Regulations for Traditional Health Practitioners in the Use of Medical Instruments and Diagnostic Support Tools

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Abstract
This research discusses legal certainty regarding traditional health services in the use of medical instruments and diagnostic support tools, regulated by Government Regulation No. 103 of 2014 concerning Traditional Health Services. The main focus is an analysis of the ambiguity of the norms in Article 23 paragraph (2) and Article 24 paragraphs (1) and (2), which prohibit traditional health practitioners from using modern medical instruments without clear exceptions. This study employs a normative legal approach, examining the vagueness of the regulations and their implications for traditional health practitioners. The research findings indicate that the unclear definitions of medical instruments and diagnostic support tools, as well as their exceptions, create legal uncertainty for practitioners. This results in risks of legal violations, inconsistency in enforcement, and confusion in the field. Therefore, a revision of the regulations is necessary to provide classifications of permitted instruments and more detailed guidelines to achieve better legal certainty.

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Introduction

Health development, as part of national development, aims to enhance awareness, willingness, and the ability to live healthily for every individual, in order to achieve the highest possible degree of public health as an investment in the development of socially and economically productive human resources. Health development, as mandated by Law Number 17 of 2023 concerning Health and Presidential Regulation Number 72 of 2012 concerning the National Health System, is carried out through various efforts in the form of services at Health Service Facilities.

Traditional health services, as part of health efforts, have historically been found in Indonesia alongside conventional health services, aimed at creating a healthy, independent, and equitable society. (Raharjo, 2014) [10] In response to the developments in health development in Indonesia, Government Regulation Number 103 of 2014 concerning Traditional Health Services (hereinafter referred to as the Traditional Health Services Regulation) was established by the relevant authorities. The purpose of the Traditional Health Services Regulation, as further stipulated in Article 2 paragraph (1), is to regulate:

The purpose of this Government Regulation is to

a. Establish a traditional health service system that synergizes with conventional health services;
b. Develop a Complementary Traditional Health Service system that synergizes and can integrate with conventional health services at Health Service Facilities;
c. Provide protection to the community;
d. Improve the quality of traditional health services; and ensure legal certainty for users and providers of traditional health services.

Discussing the objectives mentioned above, particularly point b, which states: 'to develop a Complementary Traditional Health Service system that synergizes and can integrate with conventional health services at Health Service Facilities,' as further regulated in Article 23 paragraph (2) and Article 24 paragraphs (1) and (2) of the Traditional Health Services Regulation. Article 23 paragraph (2) states, 'Traditional healers are prohibited from using medical instruments and diagnostic support tools.' Then, Article 24 paragraph (1) states, 'Traditional health practitioners are prohibited from using medical instruments and diagnostic support tools.' In both Article 23 paragraph (2) and Article 24 paragraph (1), there is the phrase 'Prohibited from using medical instruments and diagnostic support tools.' This phrase indicates that in traditional health services, there is a prohibition on using instruments that are generally used in conventional medicine. This prohibition can be interpreted to mean that traditional health services must rely on methods that are traditional in nature without the intervention of technology or modern instruments. This phrase appears to limit the use of modern medical technology in traditional healing practices. However, it does not clearly define what is meant by 'medical instruments' and 'diagnostic support tools,' leading to ambiguity in the norms.

Article 24 paragraph (2) states, 'The provisions referred to in paragraph (1) are exempt for traditional health practitioners who use medical instruments and diagnostic support tools in accordance with their methods, competencies, and authorities.' In Article 24 paragraph (2), the phrase 'exempt' causes ambiguity or confusion because the rules regarding this exemption are not clear and detailed. Additionally, the explanations for each article only state 'sufficiently clear,' without including classifications of instruments or specific conditions under which these instruments may be used. The lack of detailed explanations in these articles creates uncertainty for practitioners or regulators regarding when and how the use of these instruments can be implemented. Without a detailed explanation regarding the exemptions for medical instruments and diagnostic support tools, traditional health practitioners and those involved in regulating this sector face confusion. The absence of clear classifications allows for varied interpretations of this article, which could affect the legality of traditional health practices that utilize certain instruments.

In the general explanation, it is only stated that traditional Indonesian healing/therapy must maintain and enhance health in a holistic manner. This traditional healing method is developed for prevention, recovery, and quality of life improvement based on a biocultural body of knowledge. (Raharjo, 2013) [8] The ambiguity of the norms arises here due to the inconsistency between the articles that prohibit the use of medical instruments (Article 23 paragraph (2) and Article 24 paragraph (1)) and the exemption in the article that allows their use under certain conditions (Article 24 paragraph (2)), but without adequate explanation of what is meant by that exemption. This makes it difficult for practitioners and authorities to determine when the use of these instruments is permitted or prohibited.

The ambiguity in the aforementioned articles affects the legal certainty experienced by Traditional Health Services because the content of these articles is unclear regarding the exemptions for using medical instruments and diagnostic support tools, which lack classification as a benchmark. How is legal certainty regarding traditional health services in the use of medical instruments and diagnostic support tools?, What are the implications of the regulations on traditional health services regarding the use of medical instruments and diagnostic support tools?

Methods

This type of research is normative legal research. Normative legal research is a process of discovering legal rules, legal principles, and legal doctrines that are encountered. This research is conducted to produce new arguments, theories, or concepts as prescriptions for resolving issues. The issue in normative legal research lies in the ambiguity of the norms.

Results and Discussion

Legal Certainty for Traditional Health Services in the Use of Medical Instruments and Diagnostic Support

The ambiguity in the articles you mentioned, particularly Article 23 paragraph (2) and Article 24 paragraphs (1) and (2), does indeed have the potential to create issues regarding legal certainty, especially for traditional health services. The lack of clarity in the exceptions concerning the use of medical instruments and diagnostic aids makes these regulations difficult to understand and apply consistently. Legal certainty is a very important principle in legislation(Raharjo, 2014) [10] This principle requires the existence of clear, understandable, and consistent rules so that the parties involved, in this case, traditional health practitioners, can know what is allowed and what is not. The ambiguity in these articles creates several impacts as follows:

1. Uncertainty in the Application of Law
   - The phrase 'prohibited from using medical instruments and diagnostic aids' in Article 23 Paragraph (2) and Article 24 Paragraph (1) is not accompanied by a clear explanation of which instruments are prohibited and when exceptions may apply as stated in Article 24 Paragraph (2). This can create ambiguity for practitioners of traditional health services

2. Risk of Inconsistency in Law Enforcement
   - For law enforcement (health practitioners or other authorities), there may be varying interpretations of this regulation. As a result, there are differences in enforcement or sanctions imposed on traditional health practitioners using certain instruments. Without clear classification, it will be difficult to determine when and where the exceptions stipulated in Article 24 Paragraph (2) may apply.

3. Difficulties for Traditional Health Practitioners to Adapt
   - The ambiguity regarding which instruments can be used and what is included in 'diagnostic aids' leads traditional health practitioners to lack definitive guidance on which tools are legally safe to use. This can also hinder innovation in traditional health services, especially if there is a desire to integrate modern methods that support traditional healing.

4. Potential Legal Disputes
   - The ambiguity of this regulation can trigger legal disputes between traditional health practitioners and the government or authorities. For instance, practitioners may face legal action for using instruments deemed in violation of the regulations,

even though they believe they have complied with the exceptions outlined in Article 24 Paragraph (2). Without clear classification, practitioners lack adequate legal protection, which could potentially lead to injustices in the enforcement of the rules.

Classification of exceptions is crucial as a benchmark for traditional health practitioners. Without clear classification, this regulation lacks operational guidelines that can be applied objectively and consistently. Several reasons why the classification of exceptions is important include: (Sunggono, 2012) [12]

1. **Providing Clear Guidelines for Practitioners:** With clear classification, practitioners will know which tools they can use without violating the law.
2. **Ensuring Fair Law Enforcement:** Law enforcers need clear benchmarks to ensure that penalties are only imposed on those who truly violate the rules.
3. **Avoiding Different Interpretations:** If exceptions are explained in detail, differing interpretations in the field can be minimized.

To address this ambiguity and ensure better legal certainty for traditional health services, several steps can be taken:

1. Revision of Regulations with Additional Explanations or Clear Classifications:
   - The government could revise or provide more detailed explanations in these articles, particularly regarding exceptions for the use of medical equipment and diagnostic aids. For example, they could provide a classification of tools that may or may not be used, as well as the specific conditions that permit their use.

2. More Detailed Implementation Guidelines:
   - Create technical guidelines or implementation rules that provide clearer explanations regarding which medical devices are referred to and the specific conditions for exceptions. This will help provide operational guidance for practitioners in the field.

3. Outreach and Training for Traditional Health Practitioners:
   - The government can conduct outreach and training to provide better understanding for traditional health practitioners regarding the limitations and exceptions related to the use of medical equipment, ensuring they can comply with regulations without fear of legal repercussions.

The inconsistency in the formulation of Article 23 paragraph (2), Article 24 paragraphs (1) and (2) of the Government Regulation (PP) on Traditional Health Services with the principles of legal drafting as stipulated in Article 5 of Law Number 12 of 2011 concerning the Formation of Laws and Regulations can be analyzed through several aspects. According to Article 5 of Law 12/2011, the drafting of laws and regulations must consider several key principles, namely:

a. Clarity of Purpose
   - Articles 23 paragraph (2) and 24 paragraphs (1) and (2) regulate prohibitions and exceptions regarding the use of medical devices in traditional health services. However, the wording in these articles, particularly in the exceptions, is unclear and leads to multiple interpretations. The principle of clarity of purpose demands that legislation has a specific aim that can be easily understood by the public and the parties involved. In this case, the intended purpose of the regulation is not fully clear, whether it aims to impose strict prohibitions or to allow for the use of medical devices with more detailed exceptions.

b. Institution or Appropriate Regulatory Authority
   - This principle stipulates that laws and regulations must be created by institutions that have the authority according to the legal framework. In this case, the regulation has been formally established by the authorized institution; however, the appropriate institutional framework regarding the technical implementation of traditional health services may be debatable.

c. Suitability between Types, Hierarchy, and Content Matter
   - This principle demands alignment between the type of regulation and the material being regulated, and it must be consistent with the existing hierarchy. The regulation of medical device usage in traditional health services is quite technical, and in this case, the Government Regulation (PP) is the appropriate type of regulation to govern the technical aspects of health services. Regarding the hierarchy, the PP is already in accordance; however, issues arise concerning the content matter, which lacks detail, particularly regarding exceptions in the use of medical devices.

d. Implemented
   - Laws and regulations must be realistic and implementable. The existing articles create confusion due to ambiguous rules concerning exceptions for the use of medical devices. The lack of clarity in the wording makes it difficult for traditional health service providers to understand the clear boundaries related to the use of such devices, which could ultimately lead to inconsistent implementation. These articles are challenging to implement effectively in the field because of the unclear wording of the exceptions, which potentially leads to various interpretations.

e. Utulity dan Effectiveness
   - Regulations must be useful and provide tangible, effective results for the intended goals. The lack of clarity in the exceptions for the use of medical devices can render this regulation less effective. In practice, this can lead to confusion among traditional health practitioners regarding which devices are permissible and which are not, as well as when the exceptions apply.

f. Clarity of Formulation, and
   - This principle demands that every regulation be clearly formulated, avoiding ambiguous meanings, and be easily understood by all parties involved. Articles 23 paragraph (2) and 24 paragraphs (1) and (2) do not provide sufficient clarity regarding the exceptions to the use of medical devices. In the explanation of these articles, it is merely stated as

"sufficiently clear" without providing detailed classifications regarding the intended exceptions, leading to varying interpretations. This regulation fails to meet the principle of clarity of formulation because it does not provide clear boundaries or detailed classifications regarding which medical devices are permissible or prohibited in traditional health services.

g. Openess
- In the process of forming regulations, the principle of openness demands public participation and transparency in discussions. If the participation of traditional health practitioners is not adequately involved in the formulation of this Government Regulation, then the regulation may be considered less accommodating to their needs and understanding. The aspect of openness can be questioned if the drafting process does not involve relevant stakeholders, such as associations of traditional health services, thereby preventing them from receiving clear explanations regarding the regulations.

The formulation of Article 23 paragraph (2) and Articles 24 paragraphs (1) and (2) of the Government Regulation on Traditional Health Services exhibits several inconsistencies with the principles outlined in Article 5 of Law No. 12 of 2011 on the Formation of Legislation. Notable issues include a lack of clarity in the formulations, legal uncertainty, and difficulties in the implementation of the rules in the field. Therefore, revisions or further explanations regarding this regulation are needed to align it with the principles of good regulatory formation and to provide legal certainty and clarity for practitioners in the field of traditional health services.

Implications of Traditional Health Services in Using Medical Equipment and Diagnostic Support Tools

The use of medical equipment and diagnostic support tools in traditional health services indeed brings various complex implications, both positive and negative. On one hand, this can enhance the quality of services and assist in the integration with modern medicine. However, on the other hand, without clear regulations and adequate training, the use of these tools could lead to significant legal, ethical, and social issues.(Raharjo, 2016) [8] Below is a further explanation of both sides of these implications:

1. Positive Implications

A. Improving Service Quality
- **Diagnostic Accuracy**: The use of modern diagnostic tools can assist traditional health practitioners in improving diagnostic accuracy. Tools such as ultrasonography (USG), X-rays, or electrocardiograms (ECG) can provide more detailed information about a patient's health condition, allowing for more precise and effective treatment.
- **Increased Patient Trust**: The use of diagnostic tools can enhance patients' trust in the services provided, as the approach relies not only on intuition or experience but also on more objective medical data. This can give patients confidence that their care is informed by reliable, evidence-based information.

b. Integration with Modern Medicine
- **Use of Medical Tools:** The use of medical devices can promote integration between traditional and modern medicine. For instance, after performing a diagnosis with modern tools, traditional treatments can be more precisely targeted. This allows for a holistic approach that combines the best of both worlds.
- **Multidisciplinary Collaboration**: The use of modern tools can open up opportunities for collaboration between traditional health practitioners and modern medical professionals, such as doctors or specialists. This collaboration can improve the quality of care and provide patients with a broader range of treatment options.

c. Innovation Development in Traditional Medicine
- The use of modern diagnostic technology can stimulate innovation in traditional medicine. For example, technology used to diagnose diseases can be adapted to monitor a patient's progress after receiving traditional treatment. This supports the development of evidence-based medicine within traditional health practices.

2. Negative Implications

a. Legal issues
- Regulatory Uncertainty**:** Without clear regulations regarding when and how medical equipment can be used by traditional health practitioners, this can lead to problems. Practitioners may face legal issues if they are seen as exceeding their authority in using medical tools that should be under the control of conventional medical personnel.
- Potential Legal Violations**:** If there is no clear classification regarding the medical tools that may be used, traditional health practitioners could find themselves entangled in legal issues related to malpractice or violations of medical regulations.

b. Ethical and Professional Concern
- Credibility and Authority: The use of modern medical tools by traditional health practitioners could raise ethical issues regarding their credibility and authority. Do they have enough expertise to use these tools safely and correctly? Improper use of tools may diminish public trust in traditional medicine.
- Misdiagnosis or Misuse of Tools: Without adequate training, traditional practitioners could misuse tools, potentially leading to misdiagnosis or even endangering patient safety. This could harm patients and tarnish the reputation of traditional medicine.

C. Social and Culture
- Diminution of Traditional Cultural Values**:** The use of modern tools in traditional health practices might be perceived as diminishing the traditional values highly regarded by some communities. Traditional medicine is often valued for its natural and holistic approach. The presence of modern medical tools may be seen as an interference that undermines the essence of traditional healing.
- Resistance from Traditional Communities**:** There is

a potential for rejection from more conservative communities or those who highly value natural healing. They may feel that modern medical tools contradict their values and beliefs about healing methods passed down through generations.

D. Economic
- Higher Service Costs: Modern medical tools and diagnostic supports often require high operational costs. The use of these tools could increase the costs of traditional health services, which may ultimately burden patients, especially those from lower to middle-income groups.
- Commercialization of Traditional Medicine: If these tools are used excessively without clear regulations, there is a potential for commercialization in traditional health services. Practitioners may be inclined to offer technology-based services at higher costs, even when they are not always necessary.

To minimize risks and maximize benefits, the following are required:(Raharjo, 2022) [17]
1. More detailed and clear regulations regarding the limitations on the use of medical equipment in traditional medicine.
2. Adequate training for traditional health practitioners in the use of diagnostic tools.
3. A wise holistic approach that combines the strengths of traditional medicine and modern technology without undermining the essence of either.

In this way, traditional health services can continue to evolve, meet the demands of the times, and maintain their traditional values. Lon L. Fuller's view on the theory of lawmaking states that good legislation must avoid eight fatal errors. (Rudiansyah, 2021) [16] When relating this theory to Article 23 paragraph (2) and Articles 24 paragraphs (1) and (2) of the Government Regulation on Traditional Health Services, the following applies:

(1) Failure to establish rules at all, leading to absolute uncertainty

In this case, the regulations regarding the use of medical equipment in traditional health services tend not to provide adequate clarity. The exceptions for the use of medical equipment are not explained in detail, leading to uncertainty for traditional health practitioners regarding the limitations on the use of these tools.

(2) Failure to make rule public to those required to observe them

The regulations related to medical equipment are not easily understood by the general public, including traditional health practitioners. Since there is no detailed explanation of which tools are permissible and which are not, it is difficult for the involved parties to comply with these regulations.

(3) Improper use of retroactive law making

These regulations do not demonstrate retroactive application. However, if new regulations are suddenly enforced without sufficient notice, traditional health practitioners may find it challenging to adapt to the existing rules.

(4) **Failure to make comprehensible rules**

The lack of clarity regarding the exceptions for using medical equipment makes these rules difficult to understand, even for practitioners who are supposed to enforce them. Without clear explanations or classifications, there can be multiple interpretations that lead to confusion in the field.

(5) **Making rules which contradict each other**

Article 23 paragraph (2) prohibits the use of medical equipment, but Article 24 paragraph (2) provides exceptions without detailed explanations. This can be viewed as a contradiction because it is unclear when these exceptions apply or which tools are involved.

(6) **Making rules which impose requirements with which compliance is impossible**

Due to the lack of clarity regarding exceptions and the classification of permissible tools, these regulations may be difficult for traditional health practitioners to comply with. They may not know whether their actions are in accordance with the rules, leading to legal uncertainty.

(7) **Changing rules too frequently**

Although these rules may not have undergone significant changes, it is important to note that frequent changes without proper socialization can lead to confusion and uncertainty in the field. This could affect consistency in the implementation of regulations.

(8) **Discontinuity between content and practice**

The lack of clarity regarding the exceptions for using medical equipment in traditional health services may result in inconsistencies in the application of these rules. Traditional health practitioners may face confusion in the field, leading to a disconnect between the regulations on paper and their real-world enforcement.

Based on Lon L. Fuller's theory, the formulation of Article 23 paragraph (2) as well as Articles 24 paragraphs (1) and (2) in the Government Regulation on Traditional Health Services has several implications related to the eight fatal errors in lawmaking. The lack of clarity in the formulation, the potential contradictions between the existing Articles, and the difficulties in implementing the rules indicate that this regulation does not fully meet the criteria of good law according to Fuller's theory.

Conclusion

1. The ambiguity in Article 23 paragraph (2) and Article 24 paragraphs (1) and (2) regarding the use of medical equipment and diagnostic support tools indeed impacts legal certainty in traditional health services. This causes confusion, uncertainty in application, and potential legal conflicts. To address this issue, further clarification is needed in the form of revised regulations or more detailed technical guidelines, so that all parties involved have clear and consistent guidance.
2. The use of medical equipment and diagnostic support tools in traditional health services brings various complex implications, both positive and negative. On the one hand, it can improve the quality of services and assist in the integration with modern medicine. However, on the other hand, without clear regulations and adequate training, the use of these tools could cause significant legal, ethical, and social issues.

Suggestion

1. Review Article 23 paragraph (2), Article 24 paragraphs (1) and (2) of the Government Regulation on Traditional Health Services, which contains the phrase 'classification of exceptions in traditional health services in using medical equipment and diagnostic support tools.
2. Review the concept of ambiguity in the process of forming legislation, specifically in the Government Regulation on Traditional Health Services, to ensure consistency between the main body and the explanation of each Article in the regulation.

References

1. Asshiddiqie J. Pengantar Ilmu Perundang-Undangan Indonesia. Jakarta: Rajawali Pers; c2006.
2. Asshiddiqie J. Teori Hukum dan Konstitusi. Jakarta: Rajawali Pers; c2006.
3. Departemen Kesehatan RI. Rencana Pembangunan Jangka Panjang Tahun 2005-2025. Jakarta: Departemen Kesehatan; c2009.
4. Radbruch G, Rahardjo S. Ilmu Hukum. Bandung: Citra Aditya Bakti; c2006.
5. Indrati MF. Ilmu Perundang-Undangan: Proses dan Teknik Pembentukannya. Jakarta: Kanisius; 2007.
6. Kelsen H. Pure Theory of Law. Berkeley: University of California; c1967.
7. Marzuki PM. Penelitian Hukum. Jakarta: Kencana; c2009.
8. Raharjo H. Etika dan Hukum dalam Praktik Kesehatan. Jakarta: Pustaka Karya; c2016.
9. Raharjo H. Asas-Asas Pembentukan Peraturan Perundang-Undangan. Jakarta: Sinar Grafika; c2013.
10. Raharjo H. Prinsip-Prinsip Hukum Kesehatan. Jakarta: Pustaka Karya; c2014.
11. Sunggono B. Integrasi Teknologi dalam Pengobatan Tradisional. Jakarta: Rajawali Pers; c2013.
12. Sunggono B. Hukum dan Praktik Kesehatan Tradisional di Indonesia. Jakarta: Rajawali Pers; c2012.
13. Widodo D. Penggunaan Teknologi dalam Pelayanan Kesehatan Tradisional. Jakarta: Prenada Media; c2014.
14. Yuliandri. Asas-Asas Pembentukan Peraturan Perundang-Undangan yang Baik. Jakarta: Raja Grafindo Persada; c2011.
15. Utami NAT, Alawiya N. Perlindungan hukum terhadap pelayanan kesehatan tradisional di Indonesia. Volksgeist: Jurnal Ilmu Hukum dan Konstitusi; c2018.
16. Rudiansyah. Delapan kesalahan fatal dalam pembentukan undang-undang menurut Lon L. Fuller. Jurnal Ilmu Hukum; 2021:12(1).
17. Raharjo H. Strategi pengelolaan risiko dalam pengobatan tradisional. Jurnal Hukum dan Kesehatan; 2022:6(3).
18. Sunggono B. Pengobatan tradisional dan pengaruh teknologi modern. Jurnal Kesehatan dan Masyarakat; 2021:10(2).
19. Widodo D. Integrasi teknologi dalam pengobatan tradisional: Tantangan dan peluang. Jurnal Ilmu Kesehatan Tradisional; 2019:8(1).
20. Undang-Undang Nomor 12 Tahun tentang Pembentukan Peraturan Perundang-Undangan; c2011.
21. Undang-Undang Nomor 17 Tahun tentang Kesehatan; c2023.
22. Peraturan Pemerintah Nomor 103 Tahun tentang Pelayanan Kesehatan Tradisional; c2014.
23. Peraturan Presiden Nomor 72 Tahun tentang Sistem Kesehatan Nasional; c2012.