

AMENDMENT TO REGULATION OF MINISTER OF HEALTH NUMBER 58 YEAR 2014 CONCERNING STANDARD SERVICE OF HOSPITAL PHARMACY

(Regulation of the Minister of Health of R.I Number 34 Year 2016, dated July 29, 2016)

WITH THE BLESSING OF THE ONE AND ONLY GOD

MINISTER OF HEALTH REPUBLIC OF INDONESIA,

Considering:

- a. Whereas, Regulation of the Minister of Health Number 58 Year 2014 concerning Standard Service of Hospital Pharmacy still fails to comply with the requirements of common law so that it needs to be amended;
- b. Whereas, based on the consideration referred to in letter a, it is necessary to stipulate Regulation of the Minister of Health concerning amendment to Regulation of the Minister of Health Number 58 Year 2014, concerning Standard Service of Hospital Pharmacy;

In view of:

1. Law Number 36 Year 2009, concerning Health (Statute Book of the Republic of Indonesia Year 2009 Number 144, Supplement to Statute Book of the Republic of Indonesia Number 5063);
2. Law Number 44 Year 2009, concerning Hospital (Statute Book of the Republic of Indonesia Year 2009 Number 153, Supplement to Statute Book of the Republic of Indonesia Number 5072);
3. Law Number 23 Year 2014, concerning Regional Administration (Statute Book of the Republic of Indonesia Year 2014 Number 244, Supplement to Statute Book the Republic of Indonesia Number 5587) as amended several times and lately amended by Law Number 9 Year 2015 concerning Second Amendment to Law Number 23 Year 2014 concerning Regional Administration (Statute Book of the Republic of Indonesia Year

2015 Number 58, Supplement to Statute Book of the Republic of Indonesia Number 5679);

4. Government Regulation Number 72 Year 1998 concerning Safeguarding of Pharmaceutical Preparation and Health apparatus (Statute Book of the Republic of Indonesia Year 1998 Number 138, Supplement to Statute Book of the Republic of Indonesia Number 3781);
5. Government Regulation Number 51 Year 2009 concerning Pharmaceutical Work (Statute Book of the Republic of Indonesia Year 2009 Number 124, Supplement to Statute Book of the Republic of Indonesia Number 5044);
6. Presidential Decree Number 103 Year 2001 concerning Capacity, Duty, Function, Authority, Organizational Structure, and Work Procedure of Non-Department Government Institution, as amended several times and lately amended by Presidential Regulation Number 145 Year 2015 concerning the Eighth Amendment to Presidential Decree Number 103 Year 2001 concerning Capacity, Duty, Function, Authority, Organizational Structure, and Work Procedure of Non Ministry Government Institution (Statute Book of the Republic of Indonesia Year 2015 Number 322);
7. Regulation of the Minister of Health Number 64 Year 2015 concerning Organization and Work Procedure of the Ministry of Health (State Gazette of the Republic of Indonesia Year 2015 Number 1508);

DECIDES:

To stipulate:

REGULATION OF MINISTER OF HEALTH CONCERNING AMENDMENT TO REGULATION MINISTER OF HEALTH NUMBER 58 YEAR 2014 CONCERNING STANDARD SERVICE AT HOSPITAL PHARMACY.

Article I

Some provisions in Regulation of Minister of Health Number 58 Year 2014 concerning Standard Service of Hospital Pharmacy (State Gazette of the Republic of Indonesia Year 2014 Number 1223) have been amended as follows:

1. Add one figure to the provision in Article 1 so as that Article 1 now reads as follows:

Article 1

What is meant in this Regulation of Minister by:

1. Hospital shall be institution on health service providing comprehensive health service for hospitalized patients, out patients, and emergency.
2. Standard Service on Pharmacy shall be benchmark used as guideline for pharmaceutical personnel in providing service on pharmacy.
3. Pharmaceutical Service shall be any automatic service and responsible on any patient that relates with pharmaceutical preparation with the purpose to accomplish certain result to improve the patient's quality of life.
4. Prescription shall be written request from the doctor or dentist to Pharmacist either in writing form or electronic to prepare and provide medicines for patient in line with the provisions in the applicable Regulation.
5. Pharmaceutial preparation shall be medicines, medicinal stuff, traditional herbs, and cosmetics.
6. Medicine shall be stuff or stuff combination, including biological product used to give effect or to examine physiology or pathology in determining diagnosis, prevention, recovery, improving health and contraception for human being.
7. Health apparatus shall be instrument, apparatus, machine and/or implant without medicine used to prevent, diagnose, cure, and relieving pain, medical treatment of patient, health recovery of patient, and/or form the structure and repair body function.
8. Used Up Medicinal Stuff shall be health apparatus for single use which list of product is governed the statutory regulation.

9. Pharmaceutical installation shall be unit for functional operation exercising all activities on pharmaceutical service at Hospitals.
 10. Pharmacist shall be Pharmaceutical doctor that passed as Pharmacist and has read out the words of Oath of Terms of Office at Pharmacist.
 11. Pharmaceutical Technical Personnel shall be those assisting Pharmacist in exercising pharmaceutical work, consisting of Pharmacist Degree, Junior Pharmacist Expert, Pharmaceutical Analyst, and Pharmacist Junior Personnel / Pharmacist Assistant.
 12. Director General shall be Director General of the Ministry of Health responsible on pharmaceutical matter and health apparatus.
 13. Head of Medicines and Food Supervisory Agent hereinafter referred to as Head of BPOM shall be Head of Non Ministry Governmental Institution assigned the duty to carry out Administration duty on medicines and food supervision.
 14. Minister shall be Minister exercising Administration affairs on Health.
2. Insert three Articles in between Article 9 and Article 10, namely Article 9A, Article 9B, and Article 9C so as to read as follows:

Article 9A

- (1) Supervision other than exercised by the Minister, Head of Health Department of Province, and Head of Health Department of Regency/Municipality as referred to in Article 9 paragraph (1), specifically that relates to supervision of pharmaceutical preparation in the process of pharmaceutical preparation as referred to in Article 3 paragraph (1) letter a dilakukan juga oleh Kepala BPOM sesuai dengan tugas dan fungsi masing-masing.
- (2) Other than the supervision as referred to in paragraph (1), the Head of BPOM may monitor, give guidance, and management on the activity of Administration agency and the community on the supervision of pharmaceutical preparation.

Article 9B

- (1) The supervision exercised by Health Department or Province and the Health Department of Regency/ Municipality as referred to in Article 9 and supervision exercised by the Head of BPOM as referred to in Article 9A paragraph (1) must be reported periodically to the Minister.
- (2) The report referred to in paragraph (1) must be submitted at least once a year.

Article 9C

Any violation to the provisions in this Regulation of the Minister is subject to administrative penalty in line with the provisions in the statutory regulation.

Article II

This Regulation of Minister comes to force on the date it is enacted.

For public cognizance, this Regulation of Minister shall be announced by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

Dated July 29, 2016

MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

sgd.

NILA FARID MOELOEK

Enacted in Jakarta

Dated August 8, 2016

DIRECTOR GENERAL OF STATUTORY REGULATION

MINISTRY OF LAW AND HUMAN RIGHTS

OF THE REPUBLIC OF INDONESIA,

sgd.

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA

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