THE MINISTRY OF HEALTH	THE SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness
No. 32/2023/TT-BYT	*Hanoi, December 31, 2023*

CIRCULAR
Detailing a number of articles of the Law on Medical Examination and Treatment

Pursuant to the Law No. 15/2023/QH15 on Medical Examination and Treatment dated January 9, 2023;

Pursuant to Decree No. 95/2022/ND-CP dated November 15, 2022 of the Government defining the functions, tasks, powers and organizational structure of the Ministry of Health;

At the proposal of the Director of the Department of Medical Services Administration, the Director of the Agency of Science, Technology and Training, and the Director of the Department of Organization and Personnel;

The Minister of Health hereby promulgates the Circular detailing a number of articles of the Law on Medical Examination and Treatment.

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Chapter I
GENERAL PROVISIONS

Article 1. Scope of regulation

This Circular provides for:

1. Continuing medical education in medical examination and treatment as prescribed in Clause 14, Article 2 and Clause 4, Article 22 of the Law on Medical Examination and Treatment.

2. The scope of medical examination and treatment practice for professional titles as prescribed in Clause 3, Article 26 of the Law on Medical Examination and Treatment.

3. The template of medical examination and treatment practicing certificates as prescribed in Clause 5, Article 27 of the Law on Medical Examination and Treatment.

4. Recognition of quality standards applicable to medical examination and treatment establishments, which are issued by foreign or domestic organizations as prescribed at Point d, Clause 1 and Clause 4, Article 57 of the Law on Medical Examination and Treatment.

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5. Medical records and summaries of medical records as prescribed in Clause 1, Article 69 of the Law on Medical Examination and Treatment.

6. On-standby medical examination and treatment as prescribed in Clause 3, Article 70 of the Law on Medical Examination and Treatment.

7. Health standards and health check-ups as prescribed in Clause 2, Article 83 of the Law on Medical Examination and Treatment.

8. Good Clinical Practice as prescribed at Point d, Clause 4, Article 99 of the Law on Medical Examination and Treatment.

9. Regulations on organization and operation of professional councils and the process and procedures for dispute resolution upon occurrence of a medical complication as prescribed in Clause 6, Article 101 of the Law on Medical Examination and Treatment.

10. Mobilization, deployment, and designation of entities to participate in medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations as prescribed in Clause 4, Article 115 of the Law on Medical Examination and Treatment.

Article 2. Interpretation of terms

1. *Provider of continuing medical education in medical examination and treatment* means a medical examination and treatment establishment, or an educational institution that participates in training medical personnel, and a socio-professional organization specializing in medical examination and treatment that meets the requirements to provide continuing medical education in medical examination and treatment as prescribed in this Circular.

2. *Continuing medical education credit hour* means the unit of measurement for the time practitioners spend participating in one of the forms of continuing medical education, with the conversion formula prescribed in Appendix I to this Circular.

3. *Clinical testing of new techniques, new methods and medical equipment* is a scientific research activity on new techniques, new methods, and medical equipment on human volunteers to explore or determine the safety and effectiveness of new techniques, new methods, and medical equipment on human volunteers. clinical; identify and detect harmful reactions due to the effects of new techniques, new methods or medical equipment; the ease of use of medical equipment for doctors and medical staff; Validate or validate methods and assess the clinical performance of in vitro diagnostic medical equipment.

4. *Good Clinical Practice (GCP)* means a set of principles and standards for designing, conducting, performing, monitoring, inspecting, recording, analyzing, and reporting clinical trials of new techniques, methods, or medical

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equipment in order to ensure the reliability and accuracy of data and research reports, while protecting the rights, safety, and privacy of research subjects.

5. *Investigator's Brochure (IB)* means a comprehensive document containing general information about the new technique, method, or medical device being subject to a clinical trial; preclinical research data and previous-stage clinical trial data (if available).

6. *Case Report Form (CRF)* means a paper-based or electronic instrument designed to collect research data from participants in clinical trials of new techniques, methods, or medical equipment.

7. *ICD* means International Classification of Diseases.

Chapter II
CONTINUING MEDICAL EDUCATION FOR MEDICAL EXAMINATION AND TREATMENT PRACTITIONERS

Article 3. Duration of continuing medical education

1. Medical examination and treatment practitioners are obliged to participate in continuing medical education for at least 120 credit hours in 05 consecutive years (01 credit hour, for short-term training and refresher courses, is equivalent to 01 lesson).

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2. Medical examination and treatment practitioners who participate in one of the forms of continuing medical education prescribed in Articles 4, 5, 6 and 7 of this Circular, after converting to credit hours, will have the hours from different forms combined to calculate the total duration of continuing medical education .

Article 4. Continuing medical education by participating in short-term medical training and refresher courses, medical seminars or conferences suitable to the practice scope

1. Continuing medical education by participating in short-term training and refresher courses:

a) Short-term training and refresher courses on medical examination and treatment mean training courses with training programs and materials developed, assessed and issued in accordance with this Circular;

b) Short-term training and refresher courses shall be organized either offline or online, depending on the professional content of each course;

c) Organizers thereof may be medical examination and treatment establishments, educational institutions participating in training medical

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personnel, and social-professional organizations specializing in medical examination and treatment;

d) The continuing medical education provider shall develop a plan to organize the short-term training or refresher course and publicize it on its website before organization thereof;

dd) The continuing medical education program must be consistent with the scope of professional activities approved for the continuing medical education provider or be consistent with the training level of the examination and treatment fields and specialties of educational institutions tasked with the training. The continuing medical education program shall be developed in accordance with the instructions in Appendix III to this Circular and is regularly reviewed and updated to ensure scientific quality and suitability to practical needs;

e) Continuing medical education materials shall be compiled on the basis of the promulgated program and in accordance with the instructions in Appendix III to this Circular. Materials shall be regularly reviewed and updated to ensure scientific quality and suitability to practical needs;

g) Continuing medical education providers may use programs and materials issued by other providers when approved in writing by such providers;

h) The head of the continuing medical education provider shall select and assign enough lecturers for the training program;

i) Certification of participation in short-term training and refresher courses: Practitioners after completing short-term training and refresher courses shall be granted certificates in accordance with Appendix II to this Circular.

2. Continuing medical education by participating in conferences and seminars:

a) Medical conference or seminar means an event organized by a provider of continuing medical education in medical examination and treatment, with its content related to medical examination and treatment;

b) The organizer thereof shall have a scope of professional activities approved by competent authorities consistent with the content of the conference or seminar;

c) The topic and content shall be suitable for the scope of professional medical examination and treatment activities of the organizer;

d) The rapporteur shall have a scope of practice appropriate to the content of the report and topic of the conference or seminar;

dd) Form of organization: Either offline or online;

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e) Certification of participation in conferences and seminars: Practitioners participating in conferences and seminars shall be granted certificates by the respective organizers in accordance with Appendix II to this Circular.

Article 5. Continuing medical education by participating in compiling textbooks, teaching or professional materials on medical examination and treatment

1. Compiling textbooks, teaching materials or professional materials on medical examination and treatment means participating in specialized committees or groups to draft textbooks, teaching materials, professional materials, and professional processes with specific content on medical examination and treatment, which are then issued by heads of the drafting bodies.

2. Medical examination and treatment practitioners may chair or participate in specialized committees or groups to draft textbooks, teaching materials, and professional materials with content on medical examination and treatment appropriate to their scope of professional practice, which are then issued by heads of the drafting bodies.

3. Certificates of participation in compiling textbooks, teaching materials, and professional materials: Practitioners who chair or participate in compiling textbooks, teaching materials, and professional processes shall have their credit hours accredited and their certificates granted by the heads of the drafting bodies in accordance with Appendix II to this Circular.

Article 6. Continuing medical education by conducting scientific research and teaching medicine within the scope of practice

1. Continuing medical education by conducting scientific research within the scope of practice:

a) Practitioners preside over or participate in scientific and technological tasks at grassroots, ministerial, provincial and State levels or technical innovation initiatives, or write domestic and foreign scientific articles with content on medical examination and treatment, in accordance with their scope of practice. The scientific and technological tasks have been accepted under decisions, technical innovation initiatives have been recognized, and scientific articles have been published in scientific journals, newsletters, and special issues at home and abroad;

b) Certification of conducting scientific research: Practitioners, who complete scientific and technological tasks at all levels or technical innovation initiatives, and author scientific articles, shall have their credit hours accredited and their certificates granted by the heads of the units in charge of the scientific and technological tasks at all levels or technical innovation initiatives in accordance with Appendix II to this Circular.

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2. Continuing medical education by teaching medicine within the scope of practice:

a) Teaching medicine means imparting knowledge, skills, and etiquettes in medical examination and treatment within the practitioner's scope of expertise;

b) Practitioners may be assigned or invited to teach training courses to grant health diplomas or certificates with training content appropriate to their scope of medical examination and treatment practice;

c) Certificate of participation in teaching medicine: Practitioners teaching medicine within their scope of practice shall have their credit hours accredited by heads of the teaching organizations based on proof that the practitioners have taught and granted certificates in accordance with Appendix II to this Circular.

Article 7. Continuing medical education by self-updating medical knowledge and other forms

1. Self-updating medical knowledge means the process of studying, thinking, and researching medical knowledge and skills on the practitioners' own appropriate to their scope of expertise.

2. Self-updating medical knowledge and other forms include:

a) Practitioners participate in instructing theses and dissertations with content appropriate to their scope of practice and the theses and dissertations guided by the practitioners have been approved by the university-level thesis and dissertation evaluation councils;

b) Practitioners participate in thesis and dissertation evaluation councils; councils for acceptance of science and technology tasks at all levels; professional councils for assessment of training programs and materials with details related to medical examination and treatment appropriate to their scope of practice, medical review councils, and councils for professional mistakes;

c) Practitioners participate in professional activities in the field of medical examination and treatment appropriate to their scope of practice, including: direct or indirect case consultation, case analysis;

d) Participating in training courses to grant diplomas at home and abroad (other than study extensions) appropriate to their scope of medical examination and treatment practice;

dd) Participating in training courses to grant certificates in basic specialties, intensive specialties, specialized techniques, and technical transfer appropriate to their scope of medical examination and treatment practice;

3. Certification of self-updating medical knowledge and other forms: Practitioners self-updating medical knowledge and participating in other forms shall be granted certificates in accordance with Appendix II to this Circular by

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heads of the units presiding over such activities or directly managing the practitioners.

Article 8. Conversion to credit hours and certificates of participation in continuing medical education

1. Credit hours of continuing medical education forms shall be converted in accordance with Appendix I to this Circular.

2. Regarding a medical examination and treatment practitioner's continuing medical education organized by a foreign provider: The verification of participation time and the issuance of certificates with credit hours will be done by the head of the unit directly managing the practitioner, in accordance with Appendix II to this Circular.

Article 9. Responsibilities of a continuing medical education provider

1. To facilitate continuing medical education for practitioners; to monitor, manage, verify, and calculate credit hours for practitioners participating in continuing medical education activities organized by the provider.

2. Assign staff to be in charge and manage the provider's continuing medical education activities.

3. To organize continuing medical education activities in compliance with regulations and take responsibility for the quality of the continuing medical education provided by it.

4. To manage and archive continuing medical education records, programs and materials of short-term training and refresher courses, documentation of conferences and seminars on continuing medical education organized by the provider; oversee the verification for practitioners who have completed continuing medical education as prescribed in this Circular.

5. For continuing medical education providers organizing short-term training and refresher courses: Before organizing training and refresher courses, they shall be responsible for sending notices in accordance with Appendix IV to this Circular to the Ministry of Health (attention to the Agency of Science, Technology and Training) if they are under the management of the Ministry of Health or to the Ministry of Health and provincial-level Departments of Health if they are under the management of the provincial-level Departments of Health.

Chapter III
SCOPE OF PRACTICE OF PRACTITIONERS AND PRACTICING CERTIFICATE FORMS

Article 10. Principles for determining a practitioner's scope of practice

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1. Determining the scope of practice of a practitioner must be consistent with the health-related professional diplomas and certificates that have been granted to or recognized for such person in Vietnam; appropriate to the capacity to perform medical examination and treatment activities, including professional methods and techniques of the practitioner for the registered specialty.

2. The practitioner's scope of practice includes medical examination, medical treatment, ordering paraclinical tests, performing medical examination and treatment procedures, applying specialized techniques, prescribing medications, recommending care and nutrition regimens, evaluating medical examination and treatment outcomes, and providing health counseling and education to patients with respect to his/her professional title and respective regulations of the Minister of Health as prescribed in Article 11 of this Circular.

3. The quality of medical examination and treatment services and patient safety must be ensured.

4. It adapts to practical conditions, especially in specialized units, at different levels of technical expertise in medical examination and treatment, located in disadvantaged and extremely disadvantaged socio-economic regions.

5. No distinction is made between practitioners working at different levels of technical expertise in medical examination and treatment, or the duration of their practice.

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Article 11. Scope of practice of practitioners

1. Medical doctors: The scope of medical examination and treatment practice is prescribed in Appendix V to this Circular.

2. Traditional medicine doctors: The scope of medical examination and treatment practice is prescribed in Appendix VI to this Circular.

3. Preventive medicine doctors: The scope of medical examination and treatment practice is prescribed in Appendix VII to this Circular.

4. Odontostomatologist doctors: The scope of medical examination and treatment practice is prescribed in Appendix VIII to this Circular.

5. Specialist doctors:

a) Intensive care medicine specialist doctors: The scope of medical examination and treatment practice is prescribed in Appendix V and Appendix IX, Internal Medicine and Intensive Care Medicine, to this Circular;

b) Specialist dietitian: The scope of medical examination and treatment practice is prescribed in Appendix V and Appendix XV to this Circular;

c) Other specialist doctors: The scope of medical examination and treatment practice is prescribed in Appendix V and Appendix IX to this Circular, with respect to their specialties.

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6. Scope of practice of practitioners holding the professional title of assistant doctor:

a) The scope of medical examination and treatment practice is prescribed in Appendix X to this Circular (including first aid and normal medical examination and treatment techniques prescribed in Joint Circular No. 10/2015/TTLT-BYT-BNV dated May 27, 2015 of the Ministry of Health and the Ministry of Home Affairs prescribing codes and standards for professional titles of doctors, preventive medicine doctors, and assistant doctors);

b) Traditional medicine assistant doctors: The scope of medical examination and treatment practice is prescribed in Appendix XI to this Circular.

7. The scope of practice of practitioners holding the professional title of nurse is prescribed in Appendix XII to this Circular.

8. The scope of practice of practitioners holding the professional title of midwife is prescribed in Appendix XIII to this Circular.

9. The scope of practice of practitioners holding the professional title of laboratory technician is prescribed in Appendix XIV to this Circular.

10. The scope of practice of practitioners holding the professional title of clinical dietitian is prescribed in Appendix XV to this Circular.

11. The scope of practice of practitioners holding the professional title of clinical psychologist is prescribed in Appendix XVI to this Circular and encompasses providing continuous and comprehensive care services related to cognition, behavior, emotions, and psychosocial aspects for individuals, groups, and families, including the assessment of mental disorders, as well as the indication, development, and implementation of psychological interventions at medical examination and treatment establishments.

12. The scope of practice of a practitioner holding the professional title of pre-hospital emergency care provider is prescribed in Appendix XVII to this Circular.

13. The scope of practice of practitioners holding the professional title of herbalist is allowed to examine and treat diseases using specialized methods and techniques of traditional medicine and the list of techniques prescribed in Appendix XVIII to this Circular.

14. The scope of practice of owners of family passed-down herbal remedies:

a) Owners of family passed-down herbal remedies are allowed to conduct medical examination and use their family passed-down herbal remedies certified by competent authorities to treat diseases or conditions;

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b) Family passed-down herbal remedies used for treatment must have the correct ingredients, dosage form, uses (indications), dosage, and method of use;

c) They are allowed to use many family passed-down herbal remedies certified by competent authorities to treat different diseases or conditions of the same patient;

d) Owners of both family passed-down herbal remedies and family passed-down treatment methods are allowed to use them at the same time for the patients;

dd) They are not allowed to prescribe or use chemical medicinal products, herbal medicinal products, and specialized methods/techniques of modern medicine to examine or treat diseases.

15. The scope of practice of owners of family passed-down treatment methods:

a) Owners of family passed-down treatment methods are allowed to conduct medical examination and use their family passed-down treatment methods certified by competent authorities to treat diseases or conditions;

b) Family passed-down treatment methods used to treat diseases must be used with the proper procedures and for the proper diseases or conditions as approved by the competent authorities;

c) They are allowed to use multiple family passed-down treatment methods, in combination with family passed-down remedies, to treat different diseases and conditions in the same patient;

d) They are not allowed to use specialized methods/techniques of modern medicine to examine or treat diseases outside their scope of practicing family passed-down treatment methods.

Article 12. Templates of medical examination and treatment practicing licenses

The Ministry of Health, the Departments of Health of provinces and municipalities, the Ministry of National Defense, and the Ministry of Public Security issue practicing licenses using the templates provided in Appendix XIX to this Circular.

Chapter IV
RECOGNITION OF STANDARDS FOR QUALITY CONTROL OF MEDICAL EXAMINATION AND TREATMENT ESTABLISHMENTS

Article 13. Recognition of international standards and standards for quality control of medical examination and treatment establishments

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1. International standards and standards for quality control of medical examination and treatment establishments that have been accredited by the International Society for Quality in Healthcare (ISQua) shall be recognized.

2. The Department of Medical Services Administration shall review, publicly post and update them on the Ministry of Health's Portal, the website of the Department of Medical Services Administration, and the information system on management of medical examination and treatment activities.

Article 14. Criteria for recognizing standards for quality control of medical examination and treatment establishments other than those prescribed in Article 13 of this Circular

1. General criteria:

a) The standards stipulate application deadlines and methods of evaluating such standards;

b) The standards stipulate that quality certification is a voluntary activity of medical examination and treatment establishments;

c) The standards ensure scientificity and efficiency to manage the quality of each field of medical examination and treatment services;

d) The standards ensure the overall evaluation of quality characteristics: safety, effectiveness, timeliness, equity, patient-centeredness, and healthcare worker-centeredness;

dd) The standards include criteria and indicators that ensure the evaluation of all 3 quality elements: input, process and performance results.

2. Specific standards are prescribed in Form No. 1 provided in Appendix XX to this Circular.

Article 15. A dossier of application for recognition of standards for quality control of medical examination and treatment establishments

1. A written application for recognition of standards for quality control of medical examination and treatment establishments, made using Form No. 02 provided in Appendix XX to this Circular.

2. All quality control standards to be recognized.

3. A certified copy of the Certificate of registration of quality evaluation and accreditation for medical examination and treatment establishments of the quality accreditation organization as prescribed in Article 76 and Article 77 of the Government’s Decree No. 96/2023/ND-CP dated December 30, 2023 detailing a number of articles of the Law on Medical Examination and Treatment (hereinafter referred to as Decree No. 96/2023/ND-CP).

4. A certified copy of the establishment decision, business registration certificate or investment certificate of the quality accreditation organization.

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5. Documents proving that the standard has been pilot tested at medical examination and treatment establishments in Vietnam, including: a report on the pilot application of the standards; a summary of opinions from managerial staff of medical examination and treatment establishments and experts in the field of quality control.

6. A questionnaire indicating the satisfaction of criteria for recognition of standards for quality control of medical examination and treatment establishments, made using Form No. 1 provided in Appendix XX to this Circular.

Article 16. Procedures of recognition of quality control standards of medical examination and treatment establishments

1. The quality accreditation organization shall submit 01 dossier containing documents as prescribed in Article 15 of this Circular to the Ministry of Health (to the Department of Medical Services Administration).

2. An appraisal council shall be then established:

a) The appraisal council shall be established by the Minister of Health under a decision and consist of:

- A leader of the Ministry of Health, who acts as the chairperson of the council;

- A leader of the Department of Medical Services Administration, who acts as the standing vice chairperson, and a leader of the Department of Legal Affairs, who acts as the vice chairperson of the council;

- Leaders of certain Departments, Agencies and Institutes of the Ministry of Health, certain quality control experts, representatives of relevant Ministries, sectoral authorities, organizations and associations, who may be invited to become members with respect to the professional field of the standards to be recognized.

b) Assistants to the council include a secretariat headed by the Head of the Quality Control Division under the Department of Medical Services Administration and other relevant members.

3. Process for appraisal of the standards:

a) The secretariat shall review and check the completeness and validity of the dossier. If the dossier is complete and valid, the secretariat shall be responsible for comparing the quality control standards with the recognition criteria prescribed in Article 14 of this Circular and preparing an appraisal report to submit to the council;

b) The council then holds a meeting to appraise the standards, draw up a conclusion, and make the minutes;

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c) Within 20 days from the date of receiving a complete and valid dossier, as recorded on the receipt made using Form No. 03 provided in Appendix XX to this Circular, depending on the council's conclusion:

- In cases where the Council agrees to recognize the standards, the Department of Medical Services Administration shall put forward the standards of the quality accreditation organization to the Minister of Health for the latter to issue a recognition decision using Form No. 04 provided in the Appendix XX to this Circular;

- In cases where the Council does not agree to recognize the standards, within 05 working days from the date of the Council's conclusion, the Department of Medical Services Administration shall notify in writing the quality accreditation organization that submitted the application dossier, and clearly state the reason.

d) The decision to recognize the standards of the quality accreditation organization shall be publicly posted on the website of the Department of Medical Services Administration within 05 working days from the date it is issued.

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Chapter V
GOOD CLINICAL PRACTICE

Section 1. GENERAL REGULATIONS ON GOOD CLINICAL PRACTICE

Article 17. Good Clinical Practice principles and standards

Good Clinical Practice principles and standards are promulgated under Appendix XXI to this Circular by reference to the guidance of ICH and WHO.

Article 18. Cases of evaluation and inspection of compliance with Good Clinical Practice

1. First-time evaluation: To be conducted when the clinical trial-hosting establishment commences clinical trials of new techniques, new methods or medical equipment.

2. Periodic evaluation: To be conducted to maintain compliance with GCP every 03 years from the date the certificate of compliance with GCP is granted (other than ad-hoc evaluation and inspection).

3. Ad-hoc evaluation of compliance with GCP is prescribed in Article 27 of this Circular.

4. Inspection of compliance with GCP: The Ministry of Health and the provincial-level Departments of Health, depending on State governance requirements, shall inspect the compliance with GCP or integrate such

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inspection in the annual professional inspection plans or ad-hoc evaluations of compliance with GCP of trial-hosting establishments under their management.

Article 19. Levels of compliance with Good Clinical Practice

1. Level 1: The trial-hosting establishment complies with GCP in cases no corrective action is necessitated.

2. Level 2: Corrective actions are necessitated for the trial-hosting establishment to comply with GCP, but such corrective actions do not affect the accuracy and integrity of research data and the safety and health of participants in the trials of new techniques, methods, or medical equipment.

3. Level 3: The trial-hosting establishment fails to comply with GCP in the following cases:

a) Its deviation from GCP standards threatens to affect the accuracy and integrity of research data and/or the health and safety of participants in the trails of new techniques, methods, or medical equipment;

b) It commits fraud, falsification, or alteration of figures, data and documents.

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Section 2. FIRST-TIME EVALUATION OF COMPLIANCE WITH GOOD CLINICAL PRACTICE

Article 20. A dossier of application for first-time evaluation of compliance with Good Clinical Practice

1. A written application for evaluation of compliance with GCP, made using Form No. 01 provided in Appendix XXIII to this Decree.

2. A written declaration of general information about the trial-hosting establishment; its facilities, list of medical equipment; list of personnel who meet the respective conditions for evaluation of compliance with GCP; standard operating procedures (SOPs), quality control systems for clinical trials and documents to prove and confirm such declarations. Details of the dossier are instructed in Appendix XXII to this Circular.

3. A copy of operation license if the trial-hosting establishment is a medical examination and treatment establishment; A copy of the establishment decision or a copy of the business registration certificate enclosed with a copy of the certificate of scientific and technological activities if the trial-hosting establishment is a scientific and technological organization.

Article 21. Process for accepting an application dossier and evaluating the compliance with Good Clinical Practice

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1. The trial-hosting establishment shall submit 01 dossier containing documents as prescribed in Article 20 of this Circular to the Ministry of Health (to the Department of Medical Services Administration).

2. Within 10 working days after receiving a dossier, the Agency of Science, Technology and Training shall examine its completeness and validity. In cases where the dossier is complete and valid, the Agency of Science, Technology and Training shall establish an evaluation team in accordance with Article 28 of this Circular to conduct an on-site visit to the trial-hosting establishment within 15 working days.

In cases where the dossier is not complete and valid, the Agency of Science, Technology and Training will notify the trial-hosting establishment in writing.

3. The evaluation team shall pay an on-site visit to the trial-hosting establishment to evaluate its compliance with GCP according to GCP standards prescribed in Appendix XXI to this Circular.

4. Based on the results of the on-site visit to the trial-hosting establishment, the evaluation team then discuss with the trial-hosting establishment about its compliance with GCP and prepare an evaluation record using Form No. 02 provided in Appendix XXIII to this Circular, which determines the level of compliance with GCP of the trial-hosting establishment in accordance with Article 19 of this Circular.

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Article 22. Process for evaluation of compliance with Good Clinical Practice

1. The evaluation team shall announce the decision to establish the evaluation team; the purposes and details of the evaluation and the evaluation plan at the trial-hosting establishment.

2. The trial-hosting establishment then presents a summary of the organization, personnel, activities that implement and apply GCP, or other issues depending on the evaluation details.

3. The evaluation team conducts the on-site evaluation of the implementation and application of GCP at the trial-hosting establishment according to each specific evaluation criteria.

4. The evaluation team meets with the trial-hosting establishment to notify its level of compliance with GCP in accordance with Article 19 of this Circular, and any non-compliant criteria detected through the evaluation, which necessitate corrective actions (if any); discuss with the clinical drug trial-hosting establishment in cases where it disagrees with the team's evaluation for each detail.

5. Preparing and signing an evaluation record: The evaluation record shall be signed by the leader of the clinical drug trail-hosting establishment and the

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head of the evaluation team. The record must include the composition of the evaluation team, location, time, and scope of the evaluation, and also list and analyze in detail any non-compliant criteria that necessitate corrective actions (if any) by the trail-hosting establishment, referencing the respective regulations of this Circular, evaluate the level of compliance with GCP of the trial-hosting establishment in accordance with Article 19 of this Circular, and note any disagreements between the evaluation team and the trial-hosting establishment regarding the evaluation of compliance with GCP (if any). The record shall be made into 02 counterparts: 01 is archived at the trial-hosting establishment and 01 is archived at the dossier-receiving authority.

Article 23. Processing results of evaluation of compliance with Good Clinical Practice

1. In cases where the record on the evaluation of compliance with GCP concludes that the establishment hosting clinical trials of new techniques, new methods or medical equipment complies with GCP as prescribed in Clause 1, Article 19 of this Circular, within 10 working days from the date of signing the evaluation record, the Minister of Health shall assign the Agency of Science, Technology and Training to issue the GCP Certificate using Form No. 03 provided in Appendix XXIII to this Circular.

2. In cases where the record on the evaluation of compliance with GCP concludes that the establishment hosting clinical trials of new techniques, new methods or medical equipment should take corrective actions as prescribed in Clause 2, Article 19 of this Circular:

a) Within 05 working days from the date the on-site visit to the establishment hosting clinical trials of new techniques, new methods or medical equipment is completed and the evaluation record is signed, the Agency of Science, Technology and Training shall send the record of the evaluation of compliance with GCP, enclosed with a written notice of the on-compliant criteria that necessitate corrective actions to the establishment hosting clinical trials of new techniques, new methods or medical equipment;

b) After undertaking the corrective actions, the establishment hosting clinical trials of new techniques, new methods or medical equipment must send a written report, enclosed with proofs (documentation, photos, videos, certifications) that the corrective actions for the non-compliant criteria recorded in the evaluation record have been completely undertaken;

c) Within 20 days from the date of receiving the corrective action report from the establishment hosting clinical trials of new techniques, new methods or medical equipment, the Agency of Science, Technology and Training shall review the corrective action report of the establishment hosting clinical trials of new techniques, new methods or medical equipment and conclude on the

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compliance with GCP of the establishment hosting clinical trials of new techniques, new methods or medical equipment:

- In cases where the corrective actions of the establishment hosting clinical trials of new techniques, new methods or medical equipment are satisfactory: The Agency of Science, Technology and Training shall comply with Clause 1 of this Article.

- In cases where the corrective actions of the establishment hosting clinical trials of new techniques, new methods or medical equipment are unsatisfactory: The Agency of Science, Technology and Training shall issue a written request for continuing undertaking the corrective actions until they are satisfactory.

d) Within 06 months from the date the Agency of Science, Technology and Training issues a written request for corrective actions, if the trial-hosting establishment does not submit a corrective action report as requested, the submitted application dossier shall become invalid and the evaluation of compliance with GCP must be restarted from the beginning.

3. In cases where the record on the evaluation of compliance with GCP concludes that the establishment hosting clinical trials of new techniques, new methods or medical equipment fails to comply with GCP as prescribed in Clause 3, Article 19 of this Circular: Within 05 working days from the date the on-site visit to the establishment hosting clinical trials of new techniques, new methods or medical equipment is completed and the evaluation record is signed, the Agency of Science, Technology and Training Committee shall send a written notice of failure to comply with GCP, enclosed with the GCP evaluation record, to the establishment hosting clinical trials of new techniques, new methods or medical equipment and shall not issue a GCP Certificate.

4. Within 05 working days from the date of granting the GCP Certificate to the establishment, the Agency of Science, Technology and Training shall publicly post on the Portal of the Ministry of Health and the website of the Agency of Science, Technology and Training the following information:

a) Name and address of the establishment hosting clinical trials of new techniques, new methods or medical equipment that complies with GCP;

b) Full name of the person in charge of the professional expertise, number of the practicing certificate (in cases where the clinical trial-hosting establishment is a medical examination and treatment establishment);

c) GCP Certificate (if any);

d) Invalidation date of the evaluation of compliance with GCP and next periodic evaluation date;

dd) Scope of operation of the trial-hosting establishment.

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Section 3. EVALUATION OF MAINTENANCE OF COMPLIANCE WITH GOOD CLINICAL PRACTICE

Article 24. Periodic evaluation of maintenance of compliance with Good Clinical Practice

1. Periodically in December every year, the Agency of Science, Technology and Training shall publicly post on the website of the Agency of Science, Technology and Training a list of trial-hosting establishments that must be subject to evaluation of maintenance of compliance with GCP in the following year.

2. Based on the list publicly posted by the Agency of Science, Technology and Training, the trial-hosting establishment must submit a dossiers of application for evaluation of maintenance of compliance with GCP in accordance with Clause 6 of this Article to the Agency of Science, Technology and Training within at least 60 days before the expiration date of its GCP Certificate.

3. In cases where the establishment hosting clinical trials of new techniques, new methods or medical equipment fails to submit a dossier of application for periodic evaluation within the time limit prescribed in Clause 2 of this Article, within 15 working days from the deadline for the establishment to submit such a dossier, the Agency of Science, Technology and Training shall send a written request to the facility to submit the dossier of application in accordance with regulations.

4. Within 45 days from the date of the Agency of Science, Technology and Training's written request, the trial-hosting establishment must submit a report on operation and maintenance of compliance with GCP, enclosed with explanations for the late submission of the report. If after this deadline, the trial-hosting establishment does not submit a report, the Agency of Science, Technology and Training shall conduct an ad-hoc evaluation and check the establishment's maintenance of compliance with GCP in accordance with Article 27 of this Circular.

5. After submitting the dossier of application for periodic evaluation of maintenance of compliance with GCP within the prescribed time limit, the trial-hosting establishment may continue to conduct clinical trials of new techniques, new methods or medical equipment within the scope stated in the GCP Certificate until results of periodic evaluation of maintenance of compliance with GCP principles and standards are available and the compliance with GCP principles and standards is maintained.

6. A dossier of application for periodic evaluation of maintenance of compliance with GCP shall comprise:

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a) A written application for periodic evaluation of maintenance of compliance with GCP, made using Form No. 04 provided in Appendix XXIII to this Decree;

b) A summary report on clinical trials of new techniques, new methods or medical equipment of the trial-hosting establishment during the most recent 03 years from the time of the previous evaluation (other than any ad-hoc evaluation, inspection or examination by the Ministry of Health or the provincial-level Department of Health) to the date the ad-hoc evaluation is requested;

c) Updated documents on facilities, technical and personnel conditions of the trial-hosting establishment (if there are any changes).

7. The process and processing of results of the evaluation of maintenance of compliance with GCP shall comply with Article 22 and Article 23 of this Circular.

Article 25. Processing results of evaluation of maintenance of compliance with Good Clinical Practice

1. In cases where the GCP evaluation record concludes that the establishment hosting clinical trials of new techniques, new methods or medical equipment complies with GCP as prescribed in Clause 1, Article 19 of this Circular:

Within 10 working days from the date the on-site visit to the trial-hosting establishment is completed and the evaluation record is signed, the Agency of Science, Technology and Training shall issue a GCP Certificate using Form No. 03 provided in Appendix XXIII to this Circular.

2. In cases where the record on the evaluation of compliance with GCP concludes that the trial-hosting establishment should take corrective actions as prescribed in Clause 2, Article 19 of this Circular:

a) Within 05 working days from the date the on-site visit to the trial-hosting establishment is completed and the evaluation record is signed, the Agency of Science, Technology and Training shall send a written request to the trail-hosting establishment to take corrective actions and then send a corrective action report to the Agency of Science, Technology and Training;

b) Within 45 days from the date the Agency of Science, Technology and Training sends a written request, the trial-hosting establishment must completely undertake the corrective actions and send a written report, enclosed with proofs (documentation, photos, videos, certifications) that the corrective actions for the shortcomings recorded in the evaluation record have been completely undertaken;

c) Within 20 days from the date of receiving the corrective action report, enclosed with proofs (documentation, photos, videos, certifications), the

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Agency of Science, Technology and Training shall evaluate the results thereof and conclude on the trial-hosting establishment's compliance with GCP as follows:

- In cases where the remediation of the trial-hosting establishment is satisfactory: The Agency of Science, Technology and Training shall issue a GCP Certificate using Form No. 03 provided in Appendix XXIII to this Circular.

- In cases where the corrective actions of the trial-hosting establishment is unsatisfactory: The Agency of Science, Technology and Training shall send a written request stating the specific corrective actions that should continue and requiring additional reports thereon. The extension period for continuing the corrective actions and sending reports is 45 days from the date of the written request.

d) Within 90 days from the date the on-site visit is completed, if the trial-hosting establishment fails to send any corrective action report or it has taken corrective actions as prescribed at Point c of this Clause but such corrective actions are unsatisfactory, the Agency of Science, Technology and Training shall send a written notice of failure to comply with GCP and, depending on the nature and extent of non-compliance, the Agency of Science, Technology and Training shall take one or more of the measures as prescribed at Points a and b, Clause 3 of this Article.

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3. In cases where the GCP evaluation record concludes that the trial-hosting establishment fails to comply with GCP as prescribed in Clause 3, Article 19 of this Circular: Within 05 working days from the date the on-site visit to the trial-hosting establishment is completed and the evaluation record is signed, based on the evaluation of the detected existing risks to the quality of trails, the health and safety of participants in the trails of new techniques, new methods, or medical equipment, the Agency of Science, Technology and Training shall send a written notice of failure to comply with GCP and, depending on the nature and extent of the non-compliance, the Agency of Science, Technology and Training shall take one or more of the following measures:

a) Request competent authorities to impose penalties on administrative violations in accordance with the law regulations on handling of administrative violations;

b) Revoke the GCP Certificate granted to the trial-hosting establishment.

4. Within 05 working days from the date of conclusion that the trial-hosting establishment maintains compliance with GCP or from the date of issuance of the decision to revoke the GCP Certificate, the Agency of Science, Technology and Training will update on the website of the Agency of Science, Technology and Training the information as prescribed in Clause 4, Article 23

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of this Circular, if the trial-hosting establishment complies with GCP, or the information about revocation of its GCP Certificate, if the trial-hosting establishment fails to maintain the compliance with GCP.

Article 26. Control of changes

1. During the period between periodic evaluations, the trial-hosting establishment must carry out procedures to apply for evaluation of compliance with GCP or report changes using Form No. 05 provided in Appendix XXIII to this Circular, if it falls into one of the following cases:

a) Change in the scope of the GCP Certificate;

b) Change in the location of clinical trials of new techniques, new methods or medical equipment; change of the position of one of the technical rooms serving clinical trials of new techniques, new methods or medical equipment (examination room, treatment room, emergency room, laboratory) at a new location;

c) Change or addition of the position of one of the technical rooms serving clinical trials of new techniques, new methods or medical equipment (examination room, treatment room, emergency room, laboratory) at the same location of the clinical trials of new techniques, new methods or medical equipment;

d) Change in administrative information about the name and address of the trial-hosting establishment, update of information related to the trial-hosting establishment, change in the names of departments and divisions of the trial-hosting establishment related to the clinical trials of new techniques, new methods or medical equipment.

2. In cases where the establishment hosting clinical trials of new techniques, new methods or medical equipment has any change as prescribed at Points a and b, Clause 1 of this Article, such establishment must submit a dossier of application for evaluation of compliance with GCP as prescribed in Article 20 of this Circular. The process of evaluation of compliance with GCP, classification and processing of results of the evaluation of compliance with GCP shall comply with Articles 22 and 23 of this Circular.

3. In cases where the trial-hosting establishment makes any change as prescribed at Points c and d, Clause 1 of this Article, such trial-hosting establishment shall send a written report on the change, enclosed with documents corresponding to the change, to the Agency of Science, Technology and Training.

Article 27. Ad-hoc evaluation of compliance with Good Clinical Practice

1. Ad-hoc evaluation of compliance with GCP shall be conducted at the trial-hosting establishment in one of the following cases:

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a) The trial-hosting establishment fails to submit a report on evaluation of maintenance of compliance with GCP as prescribed in Article 24 of this Circular;

b) The trial-hosting establishment has made any change or addition as prescribed at Point c, Clause 1, Article 26 of this Circular, and such change or addition poses a risk of affecting the accuracy and integrity of research data of the clinical trials or the safety and rights of participants in the clinical trials;

c) The establishment hosting clinical trials of new techniques, new methods or medical equipment that have been inspected by competent authorities and found to have material non-compliance with GCP principles and standards;

d) Information, feedback, or complaints have been received alleging that the establishment hosting clinical trials of new techniques, new methods, or medical equipment has material non-compliance with GCP principles and standards.

2. Dossiers, process, and procedures of ad-hoc evaluation at the trial-hosting establishment shall comply with Clauses 6 and 7, Article 24 of this Circular.

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Section 4. GOOD CLINICAL PRACTICE EVALUATION TEAM

Article 28. Composition of the evaluation team and standards of evaluation team members

1. The Minister of Health shall establish a team to evaluate compliance with GCP, which consists of:

a) A representative of the leadership of the Agency of Science, Technology and Training, who acts as the team leader;

b) A representative of the leadership of the Department of Legal Affairs, who acts as the deputy head of the team;

c) A representative of the leadership of the Department of Medical Equipment and Works, who acts as the deputy head of the team (in cases where the team conducts evaluation of compliance with GCP by an establishment hosting trials of medical equipment);

d) Members who are representatives of units under the Ministry of Health, including: the Agency of Science, Technology and Training; the Department of Medical Services Administration; the Department of Legal Affairs; the Department of Medical Equipment and Works; the Agency of Traditional Medicine Administration; the National Ethics Committee in Biomedical Research;

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dd) A member who is a representative of the Department of Health of the province or municipality (hereinafter referred to as the provincial-level Department of Health) where the trial-hosting establishment is headquartered;

e) Members who are experts in the field of expertise related to the scope of evaluation. Members of relevant authorities and units in case of necessity;

g) A member who is an expert from the Agency of Science, Technology and Training acting as the team's secretary.

2. The standing body of the evaluation team for compliance with GCP prescribed in Clause 1 of this Article is located at the Agency of Science, Technology and Training under the Ministry of Health. The leader of the evaluation team may invite appropriate members for each specific case of evaluation.

3. Any cadre participating in the evaluation team, who is an expert in the field of expertise related to the scope of evaluation, must:

a) Hold an undergraduate degree or higher;

b) Have been trained on GCP and GCP evaluation;

c) Be honest, objective and strictly comply with rules and law regulations during the evaluation process, have no conflicts of interest with the trial-hosting establishment to be evaluated in accordance with Clause 4 of this Article.

4. Principles for assessing conflicts of interest: A member of the evaluation team is considered to have a conflict of interest with the trial-hosting establishment to be evaluated if he/she either:

a) Has worked within the last 05 years for the trial-hosting establishment to be evaluated;

b) Has participated in consulting activities within the last 05 years for the trial-hosting establishment to be evaluated;

c) Has any financial interest in the trial-hosting establishment to be evaluated; or

d) Has a spouse, child, parent, sibling, or parent's sibling or spouse or child working for the establishment hosting clinical trials of new techniques and methods or medical equipment to be evaluated.

Article 29. Responsibilities and powers of the evaluation team and responsibilities of the trial-hosting establishment

1. The evaluation team shall:

a) Evaluate all activities of the trial-hosting establishment according to the respective GCP principles and standards prescribed in Article 17 of this Circular and relevant technical and professional regulations; specifically record

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the evaluation criteria, shortcomings, and disagreements between the evaluation team and the trial-hosting establishment (if any); prepare an evaluation record;

b) Maintain confidentiality of all information related to the evaluation and all information related to the clinical trials of new techniques, new methods, or medical equipment at trial-hosting establishment, unless there is consent from the establishment or at the request of competent State authorities for the purpose of inspection, examination, or investigation.

2. The evaluation team have the rights to:

a) Inspect the entire site related to clinical trials of new techniques, new methods or medical equipment of the trial-hosting establishment;

b) Request the trial-hosting establishment to provide documents related to its clinical trials of new techniques, new methods or medical equipment;

c) Collect documents and proofs (photocopy documents, take photographs, record videos) to prove the shortcomings discovered during the evaluation process;

d) Make a record and request the trial-hosting establishment to temporarily stop clinical trials of new techniques, new methods or medical equipment if during the evaluation process the team discovers that the trial-hosting establishment has committed violations which severely affect the accuracy and integrity of research data and/or the safety and health of participants in clinical trials of new techniques, new methods, or medical equipment, and report the case to competent person for handling in accordance with regulations.

3. The trial-hosting establishment shall:

a) Organize the implementation of this Circular in accordance with the actual conditions of the establishment;

b) Ensure compliance with GCP principles and standards throughout the operation of the establishment;

c) Carry out clinical trials of new techniques, new methods or medical equipment within the scope of the license granted, based on compliance with law regulations;

d) Comply with regulations on time limits, dossiers, and procedures for evaluation of compliance with GCP in accordance with this Circular;

dd) Subject to ad-hoc inspection, examination and evaluation of maintenance of compliance with GCP by competent State authorities in accordance with the law regulations.

Chapter VI

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HEALTH CHECK-UP STANDARDS AND CONDUCT OF HEALTH CHECK-UPS

Section 1. GENERAL REGULATIONS ON HEALTH CHECK-UP STANDARDS AND CONDUCT OF HEALTH CHECK-UPS

Article 30. Subjects of health check-ups

1. Subjects of health check-ups:

a) Health check-ups for Vietnamese citizens and foreigners living and working in Vietnam: periodic health check-ups; health screening for study and employment purposes; health check-ups for pupils and students;

b) Health check-ups upon request;

c) Health check-ups for Vietnamese guest workers under contracts.

2. The health check-ups in this Chapter does not apply to the following cases:

a) Outpatient and inpatient medical examination at medical examination and treatment establishments;

b) Medical examination, forensic examination, forensic psychiatric evaluation;

c) Examination for issuance of injury certificates;

d) Occupational disease examination;

dd) Health check-ups for persons managed by the Ministry of National Defense and the Ministry of Public Security;

e) Health check-ups for persons working in special industries and occupations.

Article 31. Principles of performing health check-ups

1. Health check-ups are performed at medical examination and treatment establishments that have been licensed to operate medical examination and treatment in accordance with the Law on Medical Examination and Treatment.

2. Mobile health check-ups at authorities, organizations and units shall be performed in accordance with Article 79 of the Law on Medical Examination and Treatment and Articles 82 and 83 of Decree No. 96/2023/ND-CP.

3. The medical certificate granted by a competent foreign medical facility to a person shall be used in cases where Vietnam and the country or territory granting such medical certificate have a treaty or agreement on mutual recognition thereof and the validity period of such medical certificate is not more than 6 months from the date it is granted. The medical certificate must be translated into Vietnamese and such translation shall be authenticated.

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Article 32. Use of health standards to classify health status

1. The health classification of people undergoing health check-ups shall comply with the regulations of the Ministry of Health on promulgation of health classification standards for pre-employment and periodic check-ups for employees.

2. In cases of health check-ups in accordance with specialized health standards issued or recognized by competent State authorities of Vietnam, the health classification shall be based on such specialized health standards.

3. In cases of health check-ups upon request not including all specialties as per the medical certificate prescribed in this Circular, the health check-up establishment shall only examine and make conclusions for each specialty as requested and shall not classify the health status.

Article 33. Health check-up fees

1. Organizations and individuals requesting health check-ups must pay the health check-up fees to the health check-up establishment at the prices of medical examination and treatment services approved by competent State authorities or as agreed upon between the two units unless such costs are exempted or reduced as prescribed by law.

2. In cases where the person undergoing a health check-up requests two or more counterparts of the medical certificate, such person must pay an additional fee for the additional counterparts in accordance with the regulations of such medical examination and treatment establishment.

3. The collection, payment, management and use of fees from health check-ups shall comply with the law regulations.

Section 2. DOSSIERS, PROCESS, AND DETAILS OF HEALTH CHECK-UPS AND HEALTH STATUS CLASSIFICATION

Article 34. Health check-up application dossiers

1. A health check-up application dossier for a person aged 18 (eighteen) years or older is the medical certificate made using Form No. 01 provided in Appendix XXIV to this Circular, with his/her 04cm x 06cm portrait photograph taken on a white background within 06 (six) months before the date of submission of the health check-up application dossier.

2. A health check-up application dossier for a person under 18 (eighteen) years old is the medical certificate made using Form No. 02 provided in Appendix XXIV to this Circular, with his/her 04cm x 06cm portrait photograph taken on a white background within 06 (six) months before the date of submission of the health check-up application dossier.

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3. For a person who has lost their civil act capacity or has limited civil act capacity and requests medical examinations but is not subject to periodic health check-ups, the health check-up application dossier shall comprise:

a) A medical certificate as prescribed in Clause 1 or Clause 2 of this Article;

b) A written consent of the patient's family members as prescribed in Clause 11, Article 2 of the Law on Medical Examination and Treatment.

4. For a person subject to periodic health check-ups, the health check-up application dossier shall comprise:

a) A periodic health check-up book, made using Form No. 03 provided in Appendix XXIV to this Circular;

b) A referral letter from the authority or organization where such person is working in case of an individual periodic health check-up or the list of periodic health checkups mentioning such person's name, which is certified by the authority or organization where such person, for the periodic health check-up to be conducted under the contract.

Article 35. Health check-up process

1. People coming for a health check-up submit dossiers made using the prescribed forms at the health check-up establishment.

2. After receiving the health check-up application dossier, the health check-up establishment shall:

a) Compare the photograph in the health check-up application dossier with the person coming for the health check-up;

b) Apply an overlapping seal on the photograph after comparison in accordance with Point a of this Clause in the cases prescribed in Clauses 1, 2, and 3, Article 37 of this Circular;

c) Check and compare valid identification documents of the patient's relatives in the cases prescribed in Clause 3, Article 37 of this Circular;

d) Instruct the unit's health check-up process for the person undergoing the health check-up or the guardian of the person undergoing the health check-up (if any);

dd) The health check-up establishment shall develop, promulgate and implement its own health check-up process;

e) Deliver results and archive the health check-up application dossier.

Article 36. Details of a health check-up

1. In case of health check-ups for people aged 18 (eighteen) years or older but not subject to periodic health check-ups: The check-ups shall follow the

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contents specified in the medical certificate as outlined in Form No. 01 provided in Appendix XXIV to this Circular.

2. In case of health check-ups for people under 18 (eighteen) years old but not subject to periodic health check-ups: The check-ups shall follow the contents specified in the medical certificate as outlined in Form No. 02 provided in Appendix XXIV to this Circular.

3. In case of periodic health check-ups: The check-ups shall follow the contents specified in the periodic health check-up book as outlined in Form No. 03 provided in Appendix XXIV to this Circular.

4. Female employees, when undergoing periodic health check-ups, shall be given specialized obstetrics examination following the list prescribed in Appendix XXV to this Circular.

5. All aspects of each specialty must be fully examined. In complex cases, consultation or paraclinical tests may be required for definitive diagnosis and to determine the extent of the disease or disability, which will serve as the basis for health classification.

6. For health check-ups upon request, only the requested specialties will be examined and concluded, and no health classification will be made.

Article 37. Health classification

1. Health classification standards of people undergoing health check-ups shall comply with regulations of the Minister of Health.

2. Based on the results of the specialty examination, the person conducting such examination shall clearly record the diseases and disabilities within the specialty and classify the health status accordingly.

3. Based on the results of each specialty examination, the practitioner assigned by the health check-up establishment to make the final health classification and sign the medical certificate or periodic health check-up book (hereinafter referred to as the "concluding practitioner") shall carry out the health classification as follows:

a) Classify the health status of people undergoing health check-ups in accordance with the regulations of the Minister of Health on promulgation of health classification standards for periodic health check-ups for employees;

b) In case the person undergoing the health check-up has a disease or disability, the concluding practitioner shall advise on treatment and rehabilitation options or refer him/her for further examination and treatment.

4. After classifying the health status, the concluding practitioner must sign, clearly state his/her full name, and affix the seal of the health check-up establishment on the medical certificate or periodic health check-up book. The seal shall be the one used in official transactions of the health check-up

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establishment in accordance with law regulations on management and use of seals.

5. In cases of health check-ups in accordance with specialized health standards issued or recognized by competent state authorities of Vietnam, the health classification shall be based on such specialized health standards.

6. In cases where a health check-up is requested but does not include all the specialties as per the medical certificate form prescribed in this Circular, the medical examination and treatment establishment conducting the health check-up shall only examine and conclude on each specialty as requested by the person undergoing the check-up and shall not classify his/her health status.

Article 38. Grant and archiving of medical certificates

1. 01 (one) counterpart of the medical certificate shall be granted to the person undergoing the health check-up and 01 counterpart shall be archived at the health check-up establishment. The retention period of a medical certificate is prescribed in Section 20, Group 01 of documents on medical examination, treatment and rehabilitation attached to Circular No. 53/2017/TT-BYT dated December 29 2017 of the Minister of Health on retention periods of professional records and documents in the health sector. Periodic health check-up application dossiers shall be preserved and archived by the units managing the persons undergoing the health check-ups.

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2. In cases where the person undergoing the health check-up requests multiple medical certificate counterparts, the health check-up establishment will duplicate the medical certificate. Such duplication shall comply with the Government's Decree No. 30/2020/ND-CP dated March 5, 2020 on clerical work (hereinafter referred to as Decree No. 30/2020/ND-CP).

3. Time limits for delivering the medical certificates and periodic health check-up books:

a) In case of individual health check-ups: The health check-up establishment shall deliver the medical certificate or periodic health check-up book to the person undergoing the health check-up within 24 (twenty-four) hours from the end of the health check-up, unless additional check-up or testing is required at the request of the person performing the health check-up;

b) In case of collective health check-up under contract: The health check-up establishment shall deliver medical certificates or periodic health check-up books to the persons undergoing the health check-up in accordance with the agreement stated in the contract.

4. Validity of medical certificates and periodic health check-up results:

a) The medical certificate is valid for 12 (twelve) months from the date the health conclusion is validated by signature;

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b) Results of periodic health check-ups are valid in accordance with the law regulations.

Chapter VII
MOBILIZATION AND DEPLOYMENT OF PERSONNEL TO PARTICIPATE IN MEDICAL EXAMINATION AND TREATMENT UPON OCCURRENCE OF NATURAL DISASTERS, CATASTROPHES, GROUP-A COMMUNICABLE DISEASES OR EMERGENCY SITUATIONS

Article 39. Mobilization and deployment of personnel to participate in medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations

1. In cases where the personnel of the unit or locality do not meet the requirements for medical examination and treatment upon occurrence of a natural disaster, catastrophe, group-A communicable disease or emergency situation, in addition to mobilizing and deploying personnel with expertise meeting the requirements of the prevention and control of such natural disaster, catastrophe, group-A communicable disease or emergency situation as prescribed by law, the competent authority or person may mobilize and deploy the following personnel to participate in medical examination and treatment activities, including testing, sample collection, vaccination, first aid and emergency care:

a) Medical examination and treatment practitioners in Vietnam (including foreigners) are allowed to perform testing, vaccination, medical examination, treatment, first aid, and emergency care beyond the scope of their professional activities recorded in their practicing certificates;

b) Foreigners and Vietnamese nationals residing abroad, who have been licensed by foreign competent authorities to practice medical examination and treatment, are allowed to perform testing, vaccination, first aid, emergency care and other medical examination and treatment activities at medical facilities established to perform or assigned the task of receiving, providing first aid, managing, providing health care, and treating people infected with group-A communicable diseases, or victims of accidents, patients in need of first aid, emergency care, medical care, and treatment in natural disasters, catastrophes, or emergency situations without obtaining medical examination and treatment practicing certificates from competent State authorities of Vietnam;

c) Students and trainees of health schools; people who are licensed to practice medical examination and treatment but have not yet been granted medical examination and treatment practicing certificates may participate in testing, vaccination, medical examination and treatment of group-A

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communicable diseases, first aid, emergency care, medical examination and treatment for victims of natural disasters, catastrophes, or emergency situations.

Article 40. Grounds and competence for deployment and mobilization of personnel to participate in testing, vaccination, medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations

1. Grounds for mobilization and deployment of personnel to participate in medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations:

a) Upon request of the chairpersons of the People's Committees of the provinces and municipalities, the directors of the provincial-level Departments of Health, the chairpersons of the People's Committees of the districts, provincial cities and municipality-affiliated cities that need to support in terms of personnel to participate in testing, vaccination, medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations, made using the form provided in Appendix XXVII to this Circular;

b) Upon request of heads of medical examination and treatment establishments, establishments providing accommodation and treatment for patients of group-A communicable diseases and preventive medicine establishments that need to support in terms of personnel to participate in prevention and control of group-A communicable diseases, or participate in first aid, or treat patients in natural disasters, catastrophes or emergency situations;

c) Under decisions of the Minister of Health to deploy more personnel to support localities, medical examination and treatment establishments and preventive health establishments to strengthen the forces participating in prevention and control of group-A communicable diseases, or participate in first aid, or treat patients in natural disasters, catastrophes or emergency situations.

2. Competence for mobilization and deployment of personnel to participate in medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations:

a) The Minister of Health shall mobilize and deploy forces to participate in the prevention and control of group-A communicable diseases, participate in first aid, and treat patients in natural disasters, catastrophes or emergency situations nationwide, except for the forces managed by the Ministry of National Defense and the Ministry of Public Security;

b) Chairpersons of the People's Committees of the provinces and municipalities or the units authorized by the People's Committees of the provinces or municipalities may mobilize and deploy forces to participate in

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prevention and control of group-A communicable diseases, participate in first aid, and treat patients in natural disasters, catastrophes or emergency situations within their respective localities;

c) Heads of medical examination and treatment establishments, establishments providing accommodation and treatment for patients of group-A communicable diseases, preventive medicine establishments, and health education institutions may mobilize and deploy forces to participate in prevention and control of group-A communicable diseases, participate in first aid, and treat patients in natural disasters, catastrophes or emergency situations within their scope of management.

Article 41. Acceptance and assignment of personnel to participate in testing, vaccination, medical examination and treatment upon occurrence of natural disasters, catastrophes, group-A communicable diseases or emergency situations

1. The Directors of the provincial-level Departments of Health shall accept and assign forces mobilized by competent authorities to each establishment to participate in vaccination, testing, medical examination, care, and treatment of group-A communicable diseases, participate in first aid, and treat patients in natural disasters, catastrophes or emergency situations.

2. Heads of medical examination and treatment establishments, establishments providing accommodation and treatment for patients of group-A communicable diseases, preventive medicine establishments, and health education institutions shall accept and assign detailed tasks to each position and personnel consistent with professional requirements to participate in prevention and control of group-A communicable diseases, participate in first aid, and treat patients in natural disasters, catastrophes or emergency situations.

Chapter VIII
ON-STANDBY MEDICAL EXAMINATION AND TREATMENT

Article 42. Those who shall be on standby for medical examination and treatment

On-standby medical examination and treatment as prescribed in this Chapter applies to medical examination and treatment establishments with inpatient beds; medical examination and treatment establishments with hospital beds; pre-hospital emergency care establishments (hereinafter referred to as medical examination and treatment establishments).

Article 43. Principles for on-standby medical examination and treatment

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1. Standby shifts outside of office hours, holidays, and days off must be organized by medical examination and treatment establishments to ensure around-the-clock medical examination and treatment (24/24 hours).

2. Standby shifts must be strictly organized, with adequate personnel, means of transportation, medical equipment, and drugs for emergency.

3. Easy access to and adequate communication with positions on standby must be ensured.

4. A standby must be present before his/her standby shift commencement to receive the handover from the previous standby shift and, when the shift ends, must hand over to the next standby shift. They must not leave their positions when on standby and must carry out the orders of their superiors when on standby.

5. The on-standby roster shall be planned on a monthly basis, and the schedule is announced at least one week prior to the standby shift. The schedule shall be signed and approved by the hospital leader and posted on a bulletin board at each position on standby. Civil servants, public employees, and workers who have been assigned to be on standby in accordance with the schedule can only change their standby shift to the same level when approved by their leadership.

Article 44. Duties of positions on standby in a hospital

1. Leaders on standby:

a) Leaders who must be on standby: The director, deputy directors, professional and non-professional department heads designated by the director as leaders on standby, which must be authorized in writing.

b) Duties of a leader on standby:

- Check and supervise standby shifts in the hospital.

- Direct the resolution of difficult problems and situations that are beyond the professional capabilities of subordinate members.

- Direct the handling of unusual security and order incidents occurring in the hospital.

- Report to superiors directly managing the hospital on special and unexpected cases that occur beyond their resolution competence.

2. Clinical standby:

a) Organization of clinical standby:

- The head of the standby shift shall be a practitioner holding the position of head or deputy head of a professional department or a doctor with a postgraduate degree.

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- The clinical doctor on standby shall be a qualified practitioner who is able to independently handle tasks, and shall be held liable for such tasks.

- Nurses, midwives, and laboratory technicians shall be practitioners assigned by the hospital's director to be on clinical standby.

b) Duties of the head of a clinical standby shift:

- Manage personnel during the standby shift.

- Examine and prescribe treatment for emergency cases, newly hospitalized patients and seriously ill patients undergoing treatment with unusual developments when the department's on-standby clinical doctor cannot handle the case.

- Report and seek advice from direct leadership in cases beyond professional capacity and special cases such as suicide, epidemics, disasters, and mass emergencies.

- Notify the security guard and, at the same time, report to the leader on standby in case of loss of security and order in the hospital.

- Check and supervise positions on standby.

c) Duties of the doctor on standby:

- Receive patients hospitalized for emergency care.

- Monitor and manage patients handed over from the previous shift.

- Instruct and supervise on-standby team members to fully implement medical orders.

- Assign responsibilities to each on-standby team member to closely monitor and promptly address any adverse events in critically ill patients under level-1 care.

- Examining patients and recording medical records after each visit.

d) Duties of nurses, midwives, and medical technicians on standby:

- On-standby nurses are nurses from each department, and interdepartmental on-standby nursing can be organized as decided by the hospital's director.

- Carry out the doctor's orders and provide patient care and monitoring.

- Encourage patients to comply with hospital regulations.

- Archive medical records and take care of medicine cabinets and the department's assets.

- Identify patients with abnormal conditions or at risk of death, report to the on-standby doctor, and record all developments in the monitoring sheet.

3. Paraclinical standby:

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a) Each department shall arrange their own personnel on standby depending on their respective workload;

b) Duties of paraclinical personnel on standby: Perform diagnosis and treatment techniques as ordered by the clinical personnel on standby.

4. Logistics and administration on standby:

a) On-standby personnel in charges of pharmacy and medical equipment supplies and equipment shall be responsible for ensuring adequate supply of medications and operation of medical equipment to serve the on-standby crew;

b) On-standby personnel in charges of finance and accounting shall be responsible for ensuring the collection of hospital fees for patients who come in and out of the hospital outside of business hours;

c) On-standby personnel in charges of information technology shall be responsible for ensuring the hospital management network system operates normally;

d) On-standby personnel in charges of electricity and water supply shall be responsible for ensuring operation of generators upon occurrence of unexpected power outage; repairing abnormal electricity and water damages;

dd) On-standby personnel in charges of administrative affairs must ensure communication by phone and other forms of communications (in accordance with regulations of the medical examination and treatment establishment);

e) On-standby security guards shall be responsible for ensuring security and order in the hospital;

g) On-standby drivers shall ensure that the ambulance is ready when ordered.

5. Out-of-hospital on-call duty:

a) In addition to the personnel on standby assigned at the 4 levels of standby as mentioned above, depending on the specific circumstances of each hospital, the hospital leadership may arrange for on-call personnel out of the hospital to ensure readiness to provide professional and administrative support when needed;

c) On-call personnel out of the hospital must maintain continuous communication during their assigned on-call period and be present at the hospital when called upon.

Article 45. Details of a report on standby shift situation

1. After the standby shift, the departments on standby record all information to be reported in the standby shift logbook. Departments must organize meetings to hear reports on the standby situation of the departments on standby (clinical, paraclinical, logistics, and administration).

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2. The clinical standby report must contain developments during the standby shift regarding the following:

a) Mortality: Clearly record the patient's progress, treatment, cause of death, time of death, and specific actions taken after the patient's death;

b) Emergency cases: Clearly record the name, age, address, diagnosis, and treatment of each patient who came to the emergency department;

c) Critical conditions of inpatients: Clearly record the disease progression and treatment of each patient;

d) Medications: Summarize and report the quantity of medications used during the standby shift.

3. Paraclinical standby: Report on the situation of emergency tests and paraclinical techniques performed during the standby shift.

4. Logistic standby and administration on standby: Report the details prescribed in Clause 4, Article 44 of this Circular.

5. Leader on standby: Give general comments on the situation of the standby shift at the hospital-wide briefing.

Article 46. Standby shifts at medical examination and treatment establishments that are not hospitals but have inpatient beds or hospital beds

1. Medical examination and treatment establishments that are other than hospitals but have inpatient beds or hospital beds (unless otherwise prescribed in Clause 2 of this Article) must arrange personnel for a standby shift as follows: At least 01 practitioner holding the title of doctor or assistant doctor and 01 practitioner holding one of the following titles: nurse, midwife or laboratory technician.

2. For commune-level health stations, the personnel must be arranged for an standby shift as follows: At least 01 practitioner holding one of the following titles: doctor, assistant doctor, nurse, midwife, or laboratory technician.

Article 47. Pre-hospital emergency care on standby

1. Pre-hospital emergency care establishments (including patient transport establishments established under the Law on Medical Examination and Treatment No. 40/2009/QH12) shall organize around-the-clock emergency care on standby (including holidays and days off) in accordance with Decision No. 01/2008/QD-BYT dated January 21, 2008 of the Minister of Health on promulgation of regulations on emergency care, intensive care and poison control.

2. Medical examination and treatment establishments with the scope of pre-hospital emergency care practice must arrange:

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a) Personnel on around-the-clock standby;

b) One standby shift must ensure at least:

- 01 practitioner holding the title of doctor or assistant doctor.

- 01 practitioner holding one of the following titles: nurse, midwife or laboratory technician.

- 01 ambulance driver.

c) Personnel in the emergency standby shift prescribed at Point b of this Clause must be arranged independently of other standby shifts at the same time and can be arranged in the form of residency.

Chapter IX
ORGANIZATION AND OPERATION OF PROFESSIONAL COUNCILS, PROCESS AND PROCEDURES FOR DISPUTE RESOLUTION UPON OCCURRENCE OF A MEDICAL COMPLICATION

Article 48. Organization of professional councils

1. The organizational structure and number of members of a professional council include:

a) Chairperson of the council: 01;

b) Vice chairperson(s) of the council: 01 - 02;

c) Members: At least 03;

d) Secretary of the council: At least 01.

2. Principles for establishing a council:

a) Independence, objectivity, and no conflicts of interest shall be ensured;

b) Council members must have a scope of practice or professional qualifications related to the medical complication;

c) The number of members of the council (including the chairperson of the council) must be an odd number.

Article 49. Operation of professional councils

1. Conditions for holding a professional council's meeting: At least 2/3 of the council's members must be present.

2. The council's meeting:

a) The council may hold meeting in one or more sessions;

b) Each member of the council uses the records to make an assessment of the medical complication;

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c) The council shall discuss the matter in a collective manner, draw up a conclusion by majority based on the opinions of its member, and take accountability to the law for its conclusion;

d) The matter to be discussed at the council's meeting must be recorded in the minutes bearing all signatures of the council's members attending such meeting.

3. The conclusion of the professional council must determine the cause of the medical complication:

a) Upon occurrence of a medical complication due to the causes prescribed in Clause 2, Article 100 of the Law on Medical Examination and Treatment, it is concluded that the practitioner did not make any professional or technical mistake.

b) Upon occurrence of a medical complication due to professional and technical mistakes during medical examination and treatment, the following must be specifically concluded:

- That the practitioner commits one of the violations prescribed in Clause 1, Article 100 of the Law on Medical Examination and Treatment.

- The severity of the professional mistake and the sanctions for the practitioner (if any).

4. The written conclusion signed by the chairperson of the council must be consistent with the conclusion in the council's meeting minutes and be made in 02 counterparts, of which 01 is kept at the authority that established the council and another 01 is sent to the authority requesting the establishment of such council, unless the authority that established the council is a medical examination and treatment establishment where a medical complication occurs. The signature of the chairperson of the council must be authenticated by the authority that established the council.

5. During the council's meeting, if necessary, the council chairperson may request the authority that established the council to invite more experts to participate in the meeting without having to supplement the decision on establishment of the council.

Article 50. Process and procedures for dispute resolution upon occurrence of a medical complication

1. Process for dispute resolution applicable to hospitals under the management of the provincial-level Departments of Health (including hospitals of ministries and sectoral authorities, other than hospitals under the Ministry of National Defense and the Ministry of Public Security):

a) Upon occurrence of a medical complication, if a dispute arises and necessitates resolution, at the request of the patient, the patient's representative,

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the practitioner, or the police investigation agency, or the court, the hospital must establish a professional council as prescribed in Clause 1, Article 101 of the Law on Medical Examination and Treatment (referred to as the grassroots-level professional council);

b) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point a of this Clause, a written request to the provincial-level Department of Health to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute;

c) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point b of this Clause, a written request to the Ministry of Health to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute. The conclusion of the professional council of the Ministry of Health is final;

d) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed by the Ministry of Health, the parties may initiate legal action in court.

2. Process for dispute resolution in cases where medical examination and treatment establishments are under the management of the provincial-level Departments of Health but are not hospitals (including medical examination and treatment establishments, which are not hospitals, of ministries and sectoral authorities, other than establishments under the Ministry of National Defense and the Ministry of Public Security):

a) Upon occurrence of a medical complication, if a dispute arises and necessitates resolution, at the request of the patient, the patient's representative, the practitioner, or the police investigation agency, or the court, the establishment shall send a written request to the provincial-level Department of Health for establishing a professional council to resolve the dispute, enclosed with documentation related to the dispute;

b) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point a of this Clause, a written request to the Ministry of Health to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute. The conclusion of the professional council of the Ministry of Health is final;

c) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed by the Ministry of Health, the parties may initiate legal action in court.

3. Process for dispute resolution applicable to hospitals and infirmaries under the management of the Ministry of National Defense and the Ministry of Public Security:

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a) Upon occurrence of a medical complication, if a dispute arises and necessitates resolution, at the request of the patient, the patient's representative, the practitioner, or the police investigation agency, or the court, the hospital or infirmary must establish a professional council as prescribed in Clause 1, Article 101 of the Law on Medical Examination and Treatment (referred to as the grassroots-level professional council);

b) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point a of this Clause, a written request to the Department of Military Medicine under the Ministry of National Defense or the Department of Health under the Ministry of Public Security to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute;

c) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point b of this Clause, a written request to the Ministry of Health to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute. The conclusion of the professional council of the Ministry of Health is final;

d) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed by the Ministry of Health, the parties may initiate legal action in court.

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4. Process for dispute resolution in cases where medical examination and treatment establishments are under the management of the Ministry of National Defense or the Ministry of Public Security but are not hospitals or infirmaries, or are infirmaries ineligible for establishing professional councils:

a) Upon occurrence of a medical complication, if a dispute arises and necessitates resolution, at the request of the patient, the patient's representative, the practitioner, or the police investigation agency, or the court, the establishment shall send a written request to the Department of Military Medicine under the Ministry of National Defense or the Department of Health under the Ministry of Public Security for establishing a professional council to resolve the dispute, enclosed with documentation related to the dispute;

b) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point a of this Clause, a written request to the Ministry of Health to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute. The conclusion of the professional council of the Ministry of Health is final;

c) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed by the Ministry of Health, the parties may initiate legal action in court.

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5. Process for dispute resolution applicable to hospitals under the management of the Ministry of Health:

a) Upon occurrence of a medical complication, if a dispute arises and necessitates resolution, at the request of the patient, the patient's representative, the practitioner, or the police investigation agency, or the court, the hospital must establish a professional council as prescribed in Clause 1, Article 101 of the Law on Medical Examination and Treatment (referred to as the grassroots-level professional council);

b) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed at Point a of this Clause, a written request to the Ministry of Health to establish a professional council to resolve it shall be sent, enclosed with documentation related to the dispute. The conclusion of the professional council of the Ministry of Health is final;

c) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed by the Ministry of Health, the parties may initiate legal action in court.

6. Process for dispute resolution applicable to in cases where medical examination and treatment establishments are under the management of the Ministry of Health but are not hospitals:

a) Upon occurrence of a medical complication, if a dispute arises and necessitates resolution, at the request of the patient, the patient's representative, the practitioner, or the police investigation agency, or the court, the establishment shall send a written request to the Ministry of Health for establishing a professional council to resolve the dispute, enclosed with documentation related to the dispute. The conclusion of the professional council of the Ministry of Health is final;

b) In cases where the parties have a dispute and do not agree with the conclusion of the professional council prescribed by the Ministry of Health, the parties may initiate legal action in court.

Chapter X
MEDICAL RECORDS

Article 51. Case history, documents, and medical notes used in a medical record

1. 82 templates of medical records, documents, and medical notes are attached to this Circular, including:

a) Medical record templates prescribed in Appendix XXVIII to this Circular;

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b) Templates of documents and medical notes prescribed in Appendix XXIX to this Circular;

Article 52. Regulations on using and recording medical records

1. Regulations on using medical records:

a) Medical examination and treatment establishments use either paper-based or electronic medical records.

b) Medical examination and treatment establishments that use electronic medical records must ensure that all information fields of the medical records are filled.

2. Regulations on recording medical records:

a) Case history information and results of medical examination, paraclinical, functional exploration, and process of diagnosis, treatment, care and other relevant information during the medical treatment of the patient at the medical examination and treatment establishment shall be accurately, truthfully, and completely recorded;

b) Documentation must adhere to established professional guidelines and instructions;

c) Unambiguous, scientific language that is easy to understand and intelligible shall be used. Abbreviations should not be used in documents provided to patients, including medical record summaries, and documents transferred to other medical examination and treatment establishments, referral forms for health insurance examinations and treatments, and follow-up appointment reminders. Abbreviations used in medical records must adhere to the list of symbols and abbreviations established and approved for consistent use at the medical examination and treatment establishment;

d) Information in the medical record must clearly indicate the time and the person making the entry.

Chapter XI
IMPLEMENTATION PROVISIONS

Article 53. Effect

1. This Circular takes effect on January 01, 2024.

2. The following documents shall cease to be effective from date on which this Circular takes effect:

a) Circular No. 35/2019/TT-BYT dated December 30, 2019 of the Minister of Health on promulgation of the scope of professional operation for medical practitioners;

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b) Circular No. 55/2015/TT-BYT dated December 29, 2015 of the Minister of Health prescribing the recognition of clinical trials of new techniques and methods in medical examination and treatment;

c) Circular No. 14/2013/TT-BYT dated May 06, 2013 of the Minister of Health on "Guidelines for health check-ups";

d) Circular No. 09/2023/TT-BYT dated May 05, 2023 of the Minister of Health amending and supplementing a number of articles of Circular No. 14/2013/TT-BYT dated May 06, 2013 of the Minister of Health on "Guidelines for health check-ups";

dd) Regulations on standby in Clause 1, Part IV of Decision No. 1895/1997/QD-BYT dated September 19, 1997 on promulgation of hospital regulations;

e) Decision No. 4069/2001/QD-BYT dated September 28, 2001 of the Minister of Health on templates of medical records;

g) Medical record summary template (CV-01) supersedes the "Medical record summary template" in Appendix 4 to Circular No. 18/2022/TT-BYT dated December 31, 2022 of the Minister of Health on amending and supplementing a number of articles of Circular No. 56/2017/TT-BYT dated December 29, 2017 of the Minister of Health detailing the implementation of the Law on Social Insurance and the Law on Occupational Safety and Health in the health sector;

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h) Decision No. 1941/QD-BYT dated May 22, 2019 of the Minister of Health on promulgation of the traditional medicine medical record template to be used in traditional medicine establishments;

i) Decision No. 3730/QD-BYT dated August 5, 2021 of the Minister of Health on promulgation of amendments and supplements to rehabilitation medical record template and a number of rehabilitation notes;

k) Circular No. 41/2011/TT-BYT dated November 14, 2011 of the Minister of Health prescribing the grant of practicing certificates to medical practitioners and of operation licenses to medical examination and treatment establishments;

l) Circular No. 41/2015/TT-BYT dated November 16, 2015 of the Minister of Health amending and supplementing a number of articles of Circular No. 41/2011/TT-BYT dated November 14, 2011 of the Minister of Health prescribing the grant of practicing certificates to medical practitioners and of operation licenses to medical examination and treatment establishments;

m) Regulations on continuing medical education in medical examination and treatment prescribed in Circular No. 22/2013/TT-BYT dated August 09, 2013 of the Minister of Health guiding continued training for health personnel, which was amended and supplemented under Circular No. 26/2020/TT-BYT

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dated December 28, 2020 of the Minister of Health amending and supplementing a number of articles of Circular No. 22/2013/TT-BYT dated August 09, 2013 of the Minister of Health guiding continued training for health personnel.

Article 54. Reference clauses

In the case where the documents incorporated by reference to this Circular are replaced, amended or supplemented, the new ones shall prevail.

Article 55. Transitional provisions

1. In cases where the practitioners have been granted certificates of practice (hereinafter referred to as practicing certificates) in accordance with the Law on Medical Examination and Treatment No. 40/2009/QH12, their scope of practice is applied in accordance with this Circular.

2. For trial-hosting establishments that have been granted certificates of compliance with GCP with the scope of clinical trials of medicinal products (chemical medicinal products, herbal medicinal products, traditional drugs, biological products, therapeutic biological products), the trial-hosting establishments shall review and prepare conditions to ensure compliance with GCP principles and standards as prescribed in this Circular and send dossiers as prescribed in Article 20 of this Circular to the Agency of Science, Technology and Training.

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3. The Agency of Science, Technology and Training shall be responsible for checking and evaluating compliance with GCP based on the dossiers of the trial-hosting establishments. In cases where the dossier of the trial-hosting establishment is complete and meets the conditions prescribed in this Circular, the Ministry of Health shall assign the Agency of Science, Technology and Training to issue a certificate of compliance with GCP within the scope of the respective new technique or method and/or clinical trial of medical equipment within 20 working days from the date of receiving a complete and valid dossier.

4. The Agency of Science, Technology and Training shall conduct an on-site visit to a trial-hosting establishment in one of the following cases:

a) The trial-hosting establishment requests a certificate of compliance with GCP for medical equipment trial;

b) Documents proving the conditions of the trial-hosting establishment do not meet the regulations in this Circular;

c) The dossier is suspected of being erased or edited;

d) The trial-hosting establishment has been sanctioned by a competent authority for administrative violations related to clinical trials.

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5. In case of paying an on-site visit to the trial-hosting establishment, the evaluation results shall be processed in accordance with Article 23 of this Circular.

Article 56. Responsibilities for implementation

1. Chief of the Ministry Office, Director of the Department of Medical Services Administration, Director of the Agency of Science, Technology and Training, Director of the Agency of Traditional Medicine Administration, Directors of Departments under the Ministry of Health, Heads of ministerial authorities and units, Directors of Departments of Health of provinces and municipalities, Heads of health authorities of ministries and sectoral authorities, and relevant organizations shall be responsible for implementing this Circular.

Difficulties that arise during the implementation hereof should be reported by authorities, organizations and individuals to the Ministry of Health (attention to the Department of Medical Services Administration and the Agency of Science, Technology and Training) for consideration and settlement./.

FOR THE MINISTER
DEPUTY MINISTER

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Tran Van Thuan

** All Appendices are not translated herein.*

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