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Telemedicine and the Law

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International Bar Association Section on Legal Practice

Committee 2 (Medicine and Law)

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DRAFT INTERNATIONAL CONVENTION ON TELEMEDICINE AND TELEHEALTH

The States Parties to the Convention,

Inspired by recent advances in the provision of health care and medical education through the use of technology,

Recognizing the common interest of all mankind in the health and welfare of the peoples of the world,

Believing that the promotion of telemedicine and telehealth will contribute to the availability and quality of medical services to those in need, and hence to significant alleviation of human suffering and to improvement of health care and the quality of life for mankind,

Believing that these telemedical services should be available for the benefit of all peoples,

Recognizing that discrimination in the provision of health care services on the basis of race, color, descent, national or ethnic origin, sex or creed would be inconsistent with the principles established in the International Convention on the Elimination of all Forms of Racial Discrimination of March 7, 1966,

Recognizing the right to privacy and confidentiality in health matters,

Desiring to contribute to broad international cooperation in the scientific, legal, and ethical aspects of the use of telemedicine,

Believing that such cooperation will contribute to the development of mutual understanding and to strengthening of friendly relations between States and peoples,

Encouraging continued support for the advancement of telemedicine and its applications,

Convinced that a convention on telemedicine and telehealth will further the goal of providing all people with the highest practicably attainable standard of health care,

Have agreed as follows:

Article 1

TELEMEDICINE AND TELEHEALTH DEFINITIONS

For purposes of this Convention and unless otherwise indicated in a provision of this Convention or required by the Context the terms below shall have the following meanings:

1. Health care information is information or data, from whatever source, in any communicable form or medium, obtained in the course of the diagnosis, treatment or care of a patient, that either identifies or can readily be identified to that patient and that relates to the patient's health care or condition.
2. Telehealth refers to a diverse group of health-related activities, including health professional education, community health education, public health, research, and administration of health services.
3. Telehealth information means information used in the course of delivering health care and related services via electronic media.
4. Telemedicine means clinical or supportive medical practice delivered across distances via telecommunications and interactive video technology, performed by licensed or otherwise legally authorized individuals.
5. A telemedicine physician is a physician licensed by the appropriate body to provide health care through a telemedicine medium.

Article 2

GENERAL PRINCIPLES

1. The Convention shall be binding in all cases of telemedicine and telehealth delivered across state boundaries:
 - a. when the States are Contracting States; or
 - b. when the rules of private international law lead to the application of the law of the Contracting State.
2. For purposes of this convention, the States Parties agree that, whenever possible health care delivered through electronic means, regardless of form, shall be treated no differently from health care delivered face to face, directly between health care worker and patient. This Article includes, but is not limited to, issues of financial reimbursement that may arise in relation to this convention.
3. The States Parties shall take reasonable steps to ensure the protection and confidentiality of intellectual property developed to facilitate telemedicine, including, but not limited to, the provision of patenting or other formal recognition in accordance with national laws and international treaties.
4. State Parties shall undertake, with appropriate protection of intellectual property rights:
 - a. to foster international dissemination of scientific knowledge concerning telemedicine and telehealth equipment and associated information for the purposes of research and of provision of medical services;
 - b. to develop and implement telemedicine and telehealth technology safely and efficiently, particularly in remote, under-served or developing areas; and
 - c. to foster scientific and cultural cooperation, particularly between

industrialized and developing countries.

5. No provision of this convention may be used by any State, group or person to ends contrary to the principles set forth herein.
6. Each State Party will emphasize and encourage infrastructure development.
7. Each State Party shall ensure, through legislation or other means as appropriate, that all telemedicine and telehealth research carried on within its jurisdiction is conducted in accordance with internationally accepted medical, scientific and bioethical standards.
8. Each State Party shall endeavor to prohibit and bring to an end, by all appropriate means, discrimination by any persons, group or organization in the provision of health care services on the basis of race, color, descent, national or ethnic origin, sex or creed.
9. The singular includes the plural and the masculine includes the feminine within the text of this Convention.

Article 3

REGULATION OF TELEMEDICINE AND TELEHEALTH; AUTHORIZATION TO PRACTICE

1. State Licensure. Each State Party shall ensure that its health and medical licensing boards provide for reasonable opportunity for [full and unrestricted] licensure to physicians and other health care providers who wish to provide telehealth services.

Where sub-jurisdictions of State Parties regulate licensure requirements within the State Party's general jurisdiction, the State Party shall require such sub-jurisdictions to comply with the provisions of this Convention and ensure that sub-jurisdiction's licensure procedures are no more onerous or time consuming than is contemplated below.

2. License. No health care professional shall practice telemedicine or those activities of telehealth which would otherwise require licensure within the State Party's jurisdiction unless he

has obtained an authorization to practice issued by the competent authority of the State Party or organization recognized by the State Party to grant licensing authorization.

3. License Application. To obtain authorization to practice telehealth as provided for in Article 3.2 the applicant shall apply to the competent authority of the State Party, or to an internationally recognized organization whose standards are recognized by the State Party concerned. Each State Party shall ensure that the competent authority is clearly set out by the State Party. The following particulars and documents shall accompany the application by the applicant:

- a. the name and permanent residence address of the applicant;
- b. the address of the applicant's place of practice;
- c. a certified copy of the professional diploma or other professional certification;
- d. certification of good standing with the applicant's current professional body in the jurisdiction in which the applicant is currently practicing or a proof of inscription on the list of the Order of Physicians;
- e. description of the experience or expertise, if any, which the applicant has in the delivery of the applicant's services via telecommunications media;
- f. description of the area or practice specialty, if any, which the applicant wishes to pursue;
- g. not less than two professional references; and
- h. description of the means of communication, including, but not limited to, software to be used to practice telehealth.

4. Types of licenses. Except as limited by the provision of this convention, each State Party may establish categories of license for telehealth professionals, and may define the scope of practice applicable to each.

5. Approval Timing. Each State Party shall take all appropriate measures to ensure that the procedure for reviewing and making a determination with respect to the telehealth care license application is completed within thirty (30) days from the date on which the applicant's submission is complete. Each State Party shall ensure that incomplete applications are noted to the applicant within thirty (30) days of the date of submission of the application. Each State Party shall be entitled to extend the thirty (30) day period for a further fifteen (15) days upon notice to the applicant provided such notice is given to the applicant prior to the expiry of the thirty (30) day review period. A State Party may authorize telehealth practice at a level lower than that applied for. Refusal to grant the higher level may be appealed in the same manner and to the same extent as the State Party provides for applicants for licensure to practice conventional health care.

6. License Refusal. Authorization provided for in Article 3.2 may be refused if:

- a. the applicant has not provided the competent authority the requirement particulars and documents set out in Article 3.3; or
- b. after verification of the particulars and documents set out in Article 3.3, the competent authority of the State Party reasonably determines that the applicant cannot provide for the safety of patients in the State Party's jurisdiction in accordance with the standards of the State Party and the reasons for such a conclusion are set out in writing.

7. License Refusal Disputes. The World Health Organization may establish a non-binding mediation service to help resolve disputes regarding license refusal and/or suspension or revocation.

8. Compliance with Rules. Each State Party shall take all appropriate measures to ensure that the holder of an authorization complies with all the medical, health, legal and disciplinary

rules on the practice of medicine, other health practices or telehealth as such may apply in the State Party's jurisdiction.

9. Liability. Remedies prescribed by this Convention are intended do not deal with other potential disputes between a patient and a telemedical physician, including, but not limited to, claims arising out of misuse of patient records or claims for payment for services where no dispute exists as to the quality of the services.

10. Term of License. Authorizations granted by the competent authority of the State Party shall be valid for a period of not less than three (3) years and may be renewed for further three (3) year periods on application by the holder not less than three (3) months before expiration of the then current authorization. Notwithstanding the term, the State Party may require an annual report by the holder to confirm the particulars of the holder and the holder's activities in the preceding year.

11. Suspension or Revocation of License. The competent authority of the State Party may suspend or revoke an authorization to practice granted by such competent authority where:

- a. it is found that the applicant/holder no longer possesses the qualifications set out in Article 3.3;
- b. the particulars and documents supporting the application under Article 3.3 are found to be false or materially incorrect;
- c. where the applicant/holder is, in the reasonable determination of the competent authority, not able to conduct a practice in a reasonably safe manner or without adversely affecting the health of patients; or
without adversely affecting the health of patients; or
- d. where the applicant/holder has breached any professional, disciplinary or legal rules relating to the practice being undertaken.

12. License Appeals. Each State Party shall ensure that processes are available to an applicant/holder that will allow the applicant/holder to know in detail and in writing the determination and reasons for any negative determination relating to an application, renewal, suspension or revocation. Each State Party shall inform applicants of the remedies available to him/her under the laws of the State Party and of any time limits allowed for the exercise of such remedies.

13. Mutual Recognition. In the absence of an international licensing system, each State Party agrees to utilize a combination of consulting, mutual recognition and full licensure with the goal of moving toward mutual recognition. No State Party shall impose documentation or other requirements upon applicants beyond those reasonably necessary to ensure a reasonable standard of care for the people of the State.

14. Hospital Credentialing. Those State Parties that require specific authorization to be granted by the health care facility where telehealth care will be provided before a health care provider may provide that care in the facility will ensure that such facilities treat telehealth care providers in a manner similar to that applied to those providers whose practice brings them physically into the facility. It is the express intention of this provision that no one be treated differently solely because he is providing health care at a distance with the assistance of electronic media.

15. Prescriptions. Health care workers providing services through electronic means shall have the same authority to prescribe medications as a similar type/category of health care worker in the State Party in which the patient receiving care is located.

16. Common Standards and Guidelines. Each State Party shall work with other State Parties and with the World Health Organization to establish and implement international standards, guidelines and protocols for licensure for telehealth and telemedicine professionals, organizations, technology providers and suppliers of goods and services.

17. Harmonization. To the extent permitted by national and political norms, each State Party shall encourage the harmonization of its rules and regulations of telehealth and licensure with those of other State Parties. Further, each State Party shall encourage harmonization of the rules and regulations relating to telehealth and licensure within the sub-jurisdictions of such State Party.

Article 4

EQUIPMENT

1. All medical devices used in provision of telehealth services will be subject to the laws and regulations of the State Party in which they are located.
2. In order to reduce exposure to liability and ensure adequate delivery of telemedicine, each State Party shall require providers of telemedical services to identify and document:
 - a. all equipment (both hardware and software) used for telemedicine;
 - b. the owners and parties responsible for maintaining the equipment;
 - c. the format for transmitting medical information;
 - d. what studies are to be interpreted; and
 - e. the frequency and format of reports.
3. Each State Party will require that transmission verification procedures be developed at both local and remote sites. This may involve:
 - a. establishing well-defined procedures for confirming the receipt of the transmission;
 - b. verifying that there are no errors or omissions in the transmission or conversion of the data; and
 - c. verifying that the images received are appropriate for evaluation and rendering a diagnosis.

4. No State Party will unreasonably withhold approval of devices that promote the safe and effective delivery of telehealth care services, nor treat such devices differently from any others used in health care there solely on the basis that the subject device is to be used in telehealth.

Article 5

CONFIDENTIALITY OF RECORDS

1. Each State Party shall ensure that, except in limited circumstances, information regarding a person's physical condition, psychological condition, healthcare and treatment shall not be released without his consent.

2. To minimize the risk of, among other things, possible interception by third parties, and if intercepted, to reduce the probability that the intercepting party will be able to use or understand the information, each State Party shall ensure that transmission of medical information, including, but not limited to electronic transmissions of telemedical records to and from telemedical facilities, is done in an internationally acceptable manner.

3. Each State Party shall make the referring physician responsible to take reasonable steps to provide for safe storage and/or transmission of the patient's records by utilizing an adequate encryption system. Each State Party shall make the referring physician responsible to take reasonable steps to prevent anyone other than himself and his accredited colleagues from obtaining the encryption key. Each State Party shall make the referring physician and the telemedicine physician responsible to advise the patient that no medical record, paper or electronic, is completely confidential and that security breaches may occur with either.

4. Each State Party shall prohibit unauthorized access to telemedical records and patient information by all appropriate means, including legislation as required by circumstances.

5. For purposes of medical research and training, and when the identity of the person to whom the information relates cannot be determined, health care information may be divulged

without his express consent. All other existing and subsequent International Agreements governing the use of Human Subjects in medical research will be followed.

6. Each State Party agrees that telecommunications used **exclusively** for treatment of the sick or wounded during armed conflict will be protected in ways similar to those afforded hospitals and medical transports. Such transmissions will not be encrypted, thereby allowing adversaries and others to determine the nature of the transmission, and to determine that these non-combatant communication links pose no threat to the State Party's security. Except for the purposes identified in this paragraph, the duty of confidentiality remains binding upon anyone who may come to learn of health care information.

Article 6

COMPLIANCE

1. Each State Party shall annually report and publish its progress in complying with the terms of this Convention.
2. Each State Party agrees to support efforts on behalf of national law associations, in consultation with scientific, medical and other relevant organizations, independently to collect information concerning worldwide compliance with the provisions of this Convention.
3. Each State Party agrees to support its national law associations to participate in meetings of the World Health Organization and the International Bar Association dedicated to assessing worldwide compliance with the provisions of this Convention.

Each State Party agrees to provide due consideration to biennial reports and recommendations of the World Health Organization and the International Bar Association with regard to worldwide compliance with the provisions of this Convention.

Article 7

SIGNATURE, RATIFICATION AND ACCESSION

1. This convention shall be open to all States for signature. Any State that does not sign this

convention before its entry into force in accordance with paragraph 3 of this Article may accede to it at any time.

2. This convention shall be subject to ratification by signatory States. Instruments of ratification and instruments of accession shall be deposited with the Governments of [INSERT COUNTRIES], which are hereby designated the Depositary Governments. This Convention shall enter into force upon the deposit of instruments of ratification by five Governments including the Governments designated as Depositary Governments under this Convention.

3. For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Convention, it shall enter into force on the date of the deposit of their instruments of ratification or accession.

4. The Depositary Governments shall promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification of and accession to this Convention, the date of its entry into force and other notices.

5. This Convention shall be registered by the Depositary Governments pursuant to Article 102 of the Charter of the United Nations.

Article 8

AMENDMENTS

Any State Party to this Convention may propose amendments to this Convention. Amendments shall enter into force for each State Party to the Convention accepting the amendments upon their acceptance by a majority of the State Parties to the Convention and thereafter for each remaining State Party to the Convention on the date of acceptance by it.

Article 9

PERIODIC REVIEW

Ten years after the entry into force of this Convention, the question of the review of this Convention shall be included in the provisional agenda of the United Nations General Assembly

in order to consider, in light of past application of the Convention, whether it requires revision. The International Bar Association and other relevant international organizations are invited to produce reports and recommendations on the subject of any necessary revisions. At any time after the Convention has been in force for five years, however, and at the request of one third of the State Parties to the Convention, and with the concurrence of the majority of the State Parties, a conference of the States Parties shall be convened to review this Convention. The World Health Organization, the International Bar Association, and other relevant international organizations, shall be invited to attend this conference in the role of expert advisors to the State Parties.

Article 10

WITHDRAWAL

Any State Party to this convention may give notice of its withdrawal from the convention one year after its entry into force by written notification to the Depositary Governments. Such withdrawal shall take effect one year from the date of receipt of this notification.

Article 11

LANGUAGES

This convention, of which the texts in other languages are equally authentic, shall be deposited in the archives of the Depositary Governments. Duly certified copies of this convention shall be transmitted by the Depositary Governments to the Governments of the signatory and acceding States.