

# Temos International Healthcare Accreditation (TIHA)

## TIHA self - evaluation tool - Excellence in Medical Tourism

Extract

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## Excellence in Medical Tourism

### Introduction

Developed in 2006, the Temos Quality Systems and Temos Quality Criteria were designed to optimize the management of international patients in healthcare facilities worldwide. The quality standards are based on extensive research and feedback from many sources including healthcare providers, global insurance companies, and global assistance organizations. Additional review of the Temos Quality Systems was provided by experts and professionals with long-standing expertise who have worked for KTQ (Transparenz fuer Qualitaet im Gesundheitswesen), QHA-Trent, EFQM (European Foundation for Quality Management), ISO (International Organization for Standardization), JCI (Joint Commissior International) and local as well as national accreditation bodies.

In addition to adopting accreditation requirements and quality management for domestic as well as international patients, Temos "Excellence in Medical Tourism" accredited organizations are able to meet the demands of international patients and provide special services to medical tourists. In addition, Temos accredited organizations are able to meet the needs of international insurance and assistance companies in areas including documentation, billing, and accounting.

#### **Scope of Temos Accreditation Standards**

The purpose of the Temos accreditation is to neutrally assess, evaluate and validate the quality of medical and non-clinical services, to identify potential for improvement and to optimize medical quality as well as quality of services in the Applying Organization with the overall aim to assure continuum of care for patients.

Any healthcare organization may apply for the "Excellence in Medical Tourism" accreditation if it fulfills the following pre-conditions:

- 1. It is operating as a licensed health care provider in its respective country, providing medical services for in- and/or outpatients and accepts international patients.
- 2. It is working to improve the quality of its medical and non-medical services through a continuous quality improvement program within its quality management system.
- 3. It has an "International Patient Department" or adequate unit managing international patients at the different phases of the process: pre-travel, on arrival, inpatient treatment, discharge, and post-treatment follow-up.
- 4. It has been managing international patients for at least two years. New organizations that are part of a group need to provide evidence about the respective experience in the group (> three years) and in the new organization (> one year).
- 5. It assures 24/7 access to multilingual staff (or interpreters) for patients and relatives.
- 6. At least 10 % of the inpatients are regional (travel within the country or cross nearby borders to receive treatment) and/or international patients.
- 7. It confirms and proves that its medical facility practices are in accordance with international standards of medical ethics, as stated in the <u>World Medical Association (WMA) International Code of Medical Ethics</u>. Breach of ethics can lead to a subsequent denial of the Temos certificate at any time after passing the Temos assessment.

The Temos Accreditation Standards are designed for the use by the whole organization.**An accreditation of selected or specific services, departments, units or doctors is not possible.** All services offered to patients are part of the accreditation process.

### Development of the Temos Accreditation Standards (TAS)

#### How were the quality criteria developed and defined for this "TAS\_version 1.0"?

This first edition of the Temos Accreditation Standards evolved from the "Temos Quality Criteria Requirements (TCR) version 10.1\_2017", the quality manual for Temos certification. It was developed

based on cooperation with and certification of more than 100 hospitals and clinics worldwide during the last ten years, feedback from our certified partners, customers, and assessors and, not least Temos' striving for improvement and own accreditation.

The Temos Standards development process is, therefore, a collaboration between Temos International and its certified partner organizations, the Temos Assessors' Advisory Board (TAAB), external experts in quality, safety and international patient management as well as current literature, evidence-based medicine, and state-of-the-art science.

The development included a step-by-step review of the different chapters including the definition of new chapters by various experts and/or groups. The Temos Accreditation Standards cover the international standards for patient and staff safety, governance, leadership, quality management, etc. as published by ISQua, WHO, CDC, EDCD, JCI, ECRI, IHI, and others. The Temos Accreditation Standards al consider new topics in international medicine where evidence about effectiveness and improved outcomes has been published, e.g. patient blood management (PBM). In addition, the Temos Accreditation Standards include the United Nations sustainability goals where applicable to healthcare and also require policies or similar documents regarding anti-corruption/bribery/fraud and ethical considerations in international patient management.

The Temos Standards Development process is divided in four main phases following the "Plan – Do – Check – Act" principles. Depending on the content of the standards to be developed or reviewed, the respective teams are put together to achieve the best possible outcome. Temos International Governing Body has the overall authority and responsibility for approving the TIHA standards used by Temos International.

The following sources were used:

- 1. International Society for Quality in Health Care. Guidelines and Principles for the Development of Health and Social Care Standards. 4th Edition Version 1.2, September 2015;
- 2. International Society for Quality in Health Care. Guidelines and Principles for the Development of Health and Social Care Standards. 5th Edition Version 1.0, September 2018;
- 3. Review of the German and international literature for evidence-based guidelines, processes and best practice. Respective sources are listed at the end of each chapter;
- 4. Feedback and input from Temos certified partners by the "Temos Customer Feedback Form" and communication (personal and in writing) with customers;
- 5. Feedback and input from Temos assessors by the "Temos Assessors' Feedback Form" and communication (personal and in writing) with assessors;
- 6. Discussion with and feedback from the Temos Assessors' Advisory Board (TAAB) and the Temos Medical Board on the development and respective guidance;
- 7. Input from external experts with specific knowledge (Swiss Approval International, epos, and others).

In summary and as a result of the above-mentioned sources, but especially due to the Temos assessors' ten years' experience with Temos certification programs and our customers' feedback, these Temos International Healthcare Accreditation Standards contain "new" standards, focused and detailed standards as well as familiar standards that provide guidance in continuous quality improvement and (international) patient management.

#### Are the Temos accreditation requirements available for the public?

This document is provided free of charge to all applicants and on request by the international community in compliance with the rules of Temos International copyright.

#### Relationship to other standards

It is recommended but it is not a requirement to have a national or international certification or accreditation in general quality management implemented before applying for Temos accreditation. Temos International standards focus on the management of international patients in case of an emergency for tourists, business travelers, expatriates, residents, etc. ("tourism medicine") or

selective treatment as medical tourists. The management of services for international patients implies another "challenge" for all involved parties and in particular for the organization's quality management since processes might need to be re-defined or amended and additional services are to be added to meet the particular needs of those international patients.

The Temos standards are a complete guide for quality management, safety, and international patient management, following a defined process for the development and review of the standards. However, the Temos accreditation programs should be understood as complementary to the existing quality management system applicable to all patients and filling possible gaps in services.

To avoid duplication or parallel implementation of standards Temos will accept implemented standards if provided with evidence for different chapters, e.g. for risk assessment or infection prevention, if the organization follows another accredited standard. In the different chapters of the self-evaluation questionnaire respective references are asked to be provided by the organization and will be validated during the accreditation process.

## What applies in case there are local laws or regulations related to the Temos Accreditation Standards' requirements?

As stated in different chapters of this document, the applying organization has to comply with the applicable national, local and regional laws and regulations.

In case there is a conflict between Temos International standards and a national law or regulation by local authorities, the applying organization must follow the laws, regulations, and/or requirements of the organization that has set the higher-level requirements while maintaining the national regulations at the same time.

#### How frequently are the quality criteria updated?

After a first internal review after one year, the Temos Accreditation Standards in entirety will be reviewed approximately every three years; however, there is an ongoing process of reviewing standards to ensure that they are current with international best practices. If one or more quality criteria (standards) no longer reflect up-to-date medical practice or if there are revised guidelines and evidence for changes in technologies, patient safety, quality management, international patient management, and so forth, the current version will be reviewed, revised or changed accordingly. All accredited partners, assessors and involved stakeholders will be informed (and trained) as required.

#### Feedback on standards

As part of the Temos customer care management, all customers are requested to provide feedback concerning their experience with the Temos accreditation program. This request is done by means of the TIHA Customer Feedback which includes a part dedicated to the feedback on the standards.

In addition, all Temos assessors are requested to provide feedback by means of the TIHA Assessors' Feedback provided to all team members after every onsite visit. Information provided by customers and assessors are evaluated on a monthly basis, forwarded to the standards development team and presented to the Temos Assessors' Advisory Board during the quarterly board meetings. Evaluation results are also used for assessors' trainings. In case the feedback provided is a complaint, the Temos complaint management process is initiated.

Temos International appreciates further contribution to the standards which is possible by the contact form on the Temos website <u>www.temos-international.com</u> or by email at <u>info@temos-international.com</u>.

#### Temos Accreditation Standards are effective from:

#### 01 January 2019

For organizations applying (Applying Organizations) for Temos accreditation or re-accreditation, the effective date indicates the date after which all Temos (re-)accreditations and respective assessments will be based on the Temos Accreditation Standards (version 1.0). The former Temos Quality Criteria Requirements, TCR version 10.1 will be no longer valid and used.

#### How to use this document - recommended procedure

With your application for Temos Accreditation you are provided with the Temos Standards as a PDF file (the present document) as well as an online version for which you received your individual access code and password. Both documents are identical but the online version serves as an additional tool for self-evaluation by providing the self-rating functions as described in point 6. For details please see below.

- 1. Read the document carefully and work through the Temos Standards listed in this document.
- 2. Make sure that all chapters of the document are understood by the team preparing the Temos accreditation process.
- 3. Compare the Temos Standards with your existing and implemented Quality Management System and develop your internal action plan. What has to be done and added to fulfil the requirements?
- 4. Arrange your internal time table for your action plan.
- 5. The Temos Accreditation Chart (TAC) will help you to define the needed actions. Please refer to the next paragraph.
- 6. The online version of the Temos Accreditation Standards will help you to define your current status and progress. Every standard can be rated in the frame of your self-evaluation as:
  - a. Fully met
  - b. Met
  - c. Partially met
  - d. Not met
  - e. Not applicable

The document "Temos International Healthcare Accreditation Rating and Scoring Guide" provides further information and will guide you.

7. If you have any questions please get in touch with your personal contact person at Temos or contact us at the Temos Headquarters in Germany:

Email: info@temos-international.com Phone: +49 2204 426480

#### Temos Accreditation Chart (TAC) Excellence in Medical Tourism

- 1. In parallel to your work on the Temos Standards please fill in the provided TAC (Excellence in Medical Tourism) accurately and send it back to Temos via the "Send" button on the document.
- 2. The standards listed in the Temos Accreditation Standards are mirrored by questions in the different chapters of the TAC. Thus, the TAC is supposed to guide you for your preparation and to serve you as a self-evaluation tool. Details are described in the introduction of your TAC.
- 3. If you have any questions, please get in touch with your personal contact person at Temos or directly contact Temos Headquarters in Germany:

Email:info@temos-international.comPhone:+49 2204 426480

- 4. The questionnaire is evaluated and assessed by the Temos assessors in preparation of the on-site visit of your facility.
- 5. In consultation with Temos prepare the on-site visit of the Temos assessors and inform your employees and colleagues about the Temos accreditation program.

### Accreditation Participation Requirements (APR)

In the mutual interest of Temos International and the Applying Organization the following Accreditation Participation Requirements (APR) are to be fulfilled for participation in the Temos accreditation or reaccreditation process. These APR do not replace the Temos terms and conditions but are complementary and are part of the (re-) accreditation process as stated below.

APRs are not rated as the different chapters of the standard; the organization either complies with the APR or does not comply. The non-compliance with APRs may result in a denial or withdrawal of (re-) accreditation. Further information on the individual APR's evaluation as well as the respective consequences is provided below as part of each APR.

According to the Temos Code of Ethics, any attempt and/or actions constituting bribery, fraud or corruption will result in an immediate termination of the contract. The Applying Organization is held accountable for any consequences that may result from its breach of the Code of Ethics as well as any applicable laws and regulations.

#### APR 1: Submission of documents and data

During the (re-) accreditation process the Applying Organization is asked to complete the electronic Temos Accreditation Chart (TAC, the self-evaluation questionnaire) and to submit documents, data and information as required in the respective chapters and summarized in the checklist at the end of the questionnaire. This documentation includes reports and evaluation results from external bodies like local authorities, governmental inspections, fire safety inspection results, and others.

Additional information may be requested before or during the assessors' preparation of the onsite visit.

Unless otherwise agreed, all documentation, information and data as well as the TAC are to be completed and provided by the Applying Organization to Temos International electronically and/or in hard copy at least six weeks before the onsite visit of the Temos assessors' team.

As stated in the terms and conditions, the Applying Organization is required to immediately inform Temos International about significant changes in the top management, ownership or any other essential personnel and management changes as well as any critical incidents to decide if an interim assessment or earlier re-accreditation is due. Please refer to APR 2 regarding the consequences of non-compliance.

On an annual basis, the Applying Organization is required to complete the electronic annual follow up questionnaire in a timely manner. Unless otherwise agreed, all documentation, information and data as well as the annual follow up questionnaire are to be completed by the Applying Organization and provided to Temos International within six weeks after provision of the access code to the questionnaire.

#### Consequence of non-compliance with APR 1:

Timely submission and provision of documents, information and data by the Applying Organization is crucial to assure the accurate and continuous preparation and processing of the application.

If the organization does not fulfill this requirement it will be considered at risk for denial of Temos (re-)accreditation. Failure to resolve this issue within a mutually agreed time may result in denial of (re-)accreditation.

If the failure to meet this APR results in additional costs, e.g. because the travel schedule of the assessors has to be changed, these costs are to be paid by the Applying Organization.

#### APR 2: Accurate and truthful information, documents and data

The Applying Organization must provide accurate and truthful information at all times in the (re-)accreditation process. Examples of falsification include altering the content of documents through redrafting or deleting content, or providing, hiding, and removing evidence during an assessment.

Information that must be reported to Temos includes the following:

- 1. A change in organization name and/or ownership.
- 2. Any change of the contact information and/or contact persons.
- 3. A significant increase or decrease in the volume of services.
- 4. The addition of new type(s) of health service or acquisition.
- 5. The termination of any existing health service.
- 6. A significantly altered building.
- 7. Any other important information that impacts the business operation and/or delivery of patient services.

#### Consequence of non-compliance with APR 2:

If the Applying Organization falsifies information relevant and essential to the (re-)accreditation process, either by commission or omission, its accreditation award will immediately be terminated, or, in the case of a new applicant, the Applying Organization will be ineligible for re-evaluation for one year.

#### **APR 3: Proper communication**

The Applying Organization agrees to communicate in a proper and timely manner during the (re-)accreditation process. Responsibilities are defined for the (re-)accreditation process and respective staff members must be assigned and authorized accordingly.

#### Consequence of non-compliance with APR 3:

If the Applying Organization does not fulfill its obligation of proper communication, it will be considered at risk for denial or withdrawal of Temos accreditation. Failure to resolve this issue in a mutually agreed time frame may result in denial/withdrawal of (re-)accreditation.

#### APR 4: Compliance with payment schedule

Upon acceptance of the quotation offered by Temos and order placement, the Applying Organization will receive an invoice for the pre-payment of fees (in Euro). Payment shall be made within 30 days after receipt of the invoice. No bookings and schedules will be initiated before the invoiced amount has been deposited into Temos accounts.

A second and final invoice plus travel expenses (where applicable) will be sent to the Applying Organization within 14 days after the conclusion of the on-site inspection visit. The official report, and if the organization achieves (re-)accreditation, the Temos certificate is sent immediately to the Applying Organization as soon as the final payment has reached Temos accounts and the report has been approved by the Temos Board.

#### Consequence of non-compliance with APR 4:

If the Applying Organization does not fulfill its financial obligations, it will be considered at risk for denial or withdrawal of Temos (re-)accreditation. Failure to resolve this issue in a mutually agreed time frame may result in denial/withdrawal of (re-)accreditation.

#### APR 5: Access for Temos assessors to the applying organization's premises

As part of the Temos (re-)accreditation process an onsite visit takes place to validate the information provided in the Temos Accreditation Chart (TAC) and to verify compliance with the TIHA standards. This site visit includes access to all departments and units that are part of the Applying Organization (including transfer to units that are located in other buildings) as well as access to information, documents, and data at any time during the assessment. A Confidentiality Declaration will be provided by all assessors to preserve the confidentiality of the Applying Organization's information.

Temos International reserves the right to visit the Applying Organization outside the general visiting hours, e.g. at night or unannounced at any time during the validity of the Temos certificate. In this case the Temos Assessors will present an official authorization letter from the Temos Headquarters and will identify themselves as Temos certified and authorized assessors.

#### Consequence of non-compliance with APR 5:

If the Applying Organization denies or restricts access to departments, units or information, documents and data, it will be considered at risk for denial or withdrawal of Temos (re-)accreditation. Failure to resolve this issue in a mutually agreed time frame may result in denial/withdrawal of (re-)accreditation.

#### APR 6: Interpreter services and translation

In the event interpreters are involved in translations during the preparation, onsite visit of the Temos Assessors or any follow up visit(s), the Applying Organization must assure neutrality of the respective interpreter. In addition, interpreters need to be familiar with medical terms, the hospital/clinic environment and respective vocabulary.

The Applying Organization must inform Temos International Headquarters about the assignment of interpreters at least six weeks before the onsite visit providing evidence about the qualification of the assigned interpreter(s) and respective written commitment regarding his/her neutrality. The Applying Organization shall provide confidentiality declarations for all interpreters.

#### Consequence of non-compliance with APR 6:

Delays, postponements or interruption of the Temos assessment due to unqualified translation are the responsibility of the Applying Organization. Any additional costs that result by this issue shall be paid by the Applying Organization.

#### APR 7: Presentation and publication of accreditation status

The Applying Organization shall accurately present its accreditation status in any and all media including but not limited to its website, brochures, flyers, social media, etc. and is allowed to publish the following:

- 1. The final report in part or as a whole document to whom it may concern.
- 2. The Temos logo, seal, and scanned copy of the awarded Temos certificate on the website, in brochures, flyers, other marketing material and in the frame of presentations for the duration of its validity according to the Temos policy on the use of the Temos International logos by Temos accredited partners.
- 3. Photos about the Temos accreditation visit if agreed by the persons in it.
- 4. Further information about the visit after prior written authorization from Temos Headquarters.

Temos provides each Applying Organization with three certificates (size A4) at the time of initial accreditation and every year after the annual follow up invoicing. There is no charge for the certificates. Additional copies of certificates are available on request. The certificate and all copies remain Temos' property.

Accreditation certificates must be returned or destroyed if:

- 1. A new certificate is issued due to the change of the organization's name, location, or a clerical error on the original certificate.
- 2. The organization's certificate is withdrawn or denied for any reason.

#### Consequence of non-compliance with APR 7:

False, inaccurate information, or representation capable of being misunderstood must be corrected immediately. Failure of the Applying Organization to take immediate action will place the Applying

Organization at risk for denial or withdrawal of accreditation. Further legal steps may be considered.

## Section 2 - Organization Management and Administration

# Chapter 8 - Governance, Management and Leadership in an International Patient-oriented Organization (GML)

The healthcare provider is guided by a governing body – e.g. by the board, councils, individuals, a group of owners – with ultimate authority and accountability for the overall strategic directions and modes of operation of the healthcare provider. This governing body's authority includes the decision whether or not to provide services to international patients and, if so, to extend the existing quality management system by procedures and defined processes for international patients where applicable.

Further, leadership and management structures are implemented as needed based on the size of the healthcare provider and the services offered. Clear organizational leadership support is provided for quality and safety and to reach the respective strategic and operational goals of the healthcare provider as stated in its vision and mission.

The healthcare provider complies with relevant laws, regulations and inspection requirements that are applicable for the various services offered.

All management and leadership functions are provided as defined within the organizational chart as part of the QMS.

#### GML 1: Defined and approved organizational structure

An organizational structure chart depicts the different organizational and leadership levels of the healthcare provider.

o fully met	O met	o partially met	O not met	o not applicable
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# GML 2: The structue and responsibilities of the governing entity are defined in a policy and strategic plan.

The healthcare provider possesses a governing entity; structure, strategy, services, authorities and responsibilities are defined and described in respective policies or similar document(s).

○ fully met ○ met ○ partially met ○ not met ○ not applica	able
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GML 2.1: A business plan/strategic plan or similar document describes the strategic short-, middle- and long-term goals of the organization considering existing and further needed resources and its efficient use as well as environmental and financial factors.

fully met	O met	o partially met	o not met	o not applicable
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GML 2.2: The strategic plan forms the "umbrella" under which the different departments and units follow defined "sub-plans" (organization's plans), e.g. for human resources, marketing and communication, risk management and others, that are linked to the overall strategic plan.

fully met	o met	O partially met	o not met	<ul> <li>not applicable</li> </ul>
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GML 2.3: Safety and quality policies are reviewed and approved periodically by the governing body (or the authorized responsible board or individuals) and treated as a strategic priority.

Periodic reports are sent to senior management and governing body to assure that the governing body has access to up-to-date information about the current status and progress to enable applicable measures to be taken when needed.

o fully met	° met	o partially met	o not met	o not applicable
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# GML 3: The healthcare provider is operated by a chief executive, general manager or similar position.

O fully met	° met	<ul> <li>partially met</li> </ul>	O not met	<ul> <li>not applicable</li> </ul>
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GML 3.1: The chief executive(s) is/are responsible for complying with applicable national laws, regulations and internally set rules.

o fully met	o met	<ul> <li>partially met</li> </ul>	o not met	<ul> <li>not applicable</li> </ul>
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GML 3.2: The chief executive(s) is/are responsible for the healthcare provider's day-to-day business, operating in an effective and efficient way – supported by the departments and units - to fulfill its vision and mission.

These responsibilities include but are not limited to the following: Identification and planning for the type of clinical services required to meet patient needs; implementing and reviewing policies; setting targets and goals for the future for the different departments and units through planning and budgeting; establishing and reviewing processes for achieving those targets; allocating resources to accomplish those plans; and ensuring that the defined plans are achieved by organizing, staffing, management and oversight and problem-solving. Chief executive(s) are responsible for responding to reports and requests from inspecting or regulatory agencies but may delegate specific portions to the departments and units to which the inspection refers to.

fully met	o met	o partially met	O not met	o not applicable
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GML 3.3: International Patient Department's reporting level is the top management level of the hospital.

o fully met	o met	o partially met	o not met	o not applicable
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GML 3.4: Regular meetings and communication take place between the governing body and the chief executive(s) to assure conformity with the agreed decisions and goals.

○ fully met ○ met ○ partially met ○ not met ○ not applicable

GML 4: The healthcare provider possesses an adequate number of directors, officers, and managers to assure respective leadership in all medical and non-clinical departments and units and to achieve its vision and mission.

○ fully met	o met 🛛 o	partially met	0	not met	0	not applicable
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GML 4.1: Leadership positions are identified and described in respective job descriptions including tasks, responsibilities and authorizations.

○ fully met ○ met	<ul> <li>partially met</li> </ul>	O not met	o not applicable
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GML 4.2: Directors, officers, managers and other healthcare provider leadership cooperate to develop and review the healthcare provider's services, programs, and policies to support the chief executive(s) in his/her/their work and to achieve the healthcare provider's vision and mission.

<ul> <li>fully met</li> </ul>	° met	o partially met	o not met	<ul> <li>not applicable</li> </ul>
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GML 4.3: Decisions related to purchasing are made by healthcare provider leadership considering quality and safety related implications. The decisions are based on data and information on quality, safety, and handling of the products as well as quality and safety of the supply chain including maintenance and services where applicable.

o fully met	O met	O partially met	O not met	o not applicable
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GML 4.4: Regular meetings and communication take place between the chief executive(s) and the leadership to assure conformity with the agreed decisions and goals.

o fully met	o met	o partially met	o not met	o not applicable
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GML 4.5: Regular meetings and communication take place between the leadership and associated departments and units to assure conformity with the agreed decisions and goals.

Please refer also to the chapters "Human Resources, Continuous Medical Education (CME) and training (HRET), Committees (COM), Quality Management and System Validation (QMSV).

o fully met	° met	<ul> <li>partially met</li> </ul>	o not met	o not applicable
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#### References

- 1. International Society for Quality in Healthcare. 2015. ISQua Guidelines and Principles for the Development of Health and Social Care Standards. 4th Edition Version 1.2.
- 2. Sarto, F.; Veronesi, G. 2016. Clinical leadership and hospital performance: assessing the evidence base. BMC Health Services Research. 16 (Suppl2):169. Accessed on Apr 30, 2018 https://bmchealthservres.biomedcentral.com/track/pdf/10.1186/s12913-016-1395-5
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- 4. Bucci R.V. 2014. Chapter 2 Leadership and Governance in Medicine and Business: A Practitioner's Guide, 9DOI 10.1007/978-3-319-04060-8 2. Springer International Publishing Switzerland.
- 5. Center for Healthcare GovernanceTM. 2009. The Guide to Good Governance for Hospital Boards. Accessed on Apr 30, 2018

http://trustees.aha.org/boardorientation/09-guide-to-good-governance.pdf

### Chapter 11 - Legal Aspects in International Patient Management (LAIP)

According to principles of justice each person should be treated fairly, equitable, and given his or her due. Justice also applies to distributive justice, which concerns the fair and equitable allocation of resources, benefits and burdens.

Applicable legal requirements and respective handling are considered in the different chapters of this documents, e.g. for human resources and employment, occupational medicine and staff safety, infection prevention and control, infrastructure and safety, medical services, nursing and midwifery services, etc.

Criteria included in this chapter identify and assure the following:

Throughout its operational framework, the healthcare provider establishes and maintains specific procedures in order to assure conformance with federal/state/local specific legal requirements as well as malpractice prevention with adequate insurance coverage taking into consideration international ethical codes and legislation. The healthcare provider establishes and maintains specific procedures in order to prevent fraud, corruption, and bribery.

The healthcare provider is familiar with the applicable legal requirements in the patient's home country that are to be considered and also complies with the ethical requirements for international patient management.

#### LAIP 1: General legal aspects in international patient management

LAIP 1.1: As part of the healthcare provider's risk assessment particular issues for dealing with patients from special countries are evaluated and respective risk management is in place.

Example: The US as a litigious environment with "generosity" of malpractice awards.

<ul> <li>fully met</li> </ul>	° met	O partially met	O not met	o not applicable
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LAIP 1.2: The healthcare provider assures complete documentation of the patient case and respective treatment and is able to provide evidence of all steps of the treatment process from admission until discharge.

○ fully met ○ met ○ partially met	O not met	o not applicable
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LAIP 1.3: Where patient informed consent is obtained, e.g. for surgical or other invasive procedures, in case of participation in research, studies or experimental procedures or in case photographs, videos or similar are prepared for any promotional activities, the information is provided in a language understood by the patient and the patient signs a document acknowledging his or her consent.

0	fully met	° met	C partially met	o not met	o not applicable
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LAIP 1.4: Discharge reports are complete and comprehensive and provided in a language understood by the patient and/or the following up doctor in the patient's home country.

○ fully met ○ met ○ partially met ○ not met	<ul> <li>not applicable</li> </ul>
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LAIP 1.5: A patient contract or similar defines the patient's and healthcare provider's rights and duties in a legally binding way. It contains information on how disputes are resolved.

Temos recommendation: Clearly state that disputes are to be resolved under the law of your healthcare provider's jurisdiction and that the patient cannot bring a suit elsewhere.

○ fully met ○ met	o partially met	o not met	o not applicable
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LAIP 1.6: In case where facilitators are involved, a contract clearly defines the facilitator's and healthcare provider's rights and duties, including liability, in a legally binding way.

o fully met	O met	o partially met	not met	o not applicable
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LAIP 1.7: In case of an electronic cross-border exchange of medical or other confidential information, respective regulations that apply in the different countries are followed and documentation/evidence can be provided.

fully met	° met	o partially met	o not met	o not applicable
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LAIP 1.8: Due to different countries' regulations, some papers and documents will have to be translated into a foreign language and legalized (apostilled) to be valid in the respective country. The healthcare provider has a respective procedure in place.

○ fully met ○ met	o partially met	O not met	o not applicable
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#### LAIP 2: Insurances: malpractice, accidents, and liability

LAIP 2.1: Malpractice and necessary corrective actions might result in patient harm, poor satisfaction rates, high costs, and other undesired consequences.

The healthcare provider has implemented individual measures including insurance covering malpractice/liability/indemnity, accidents (external doctors/consultants, staff, patients, visitors), natural disasters, fire, and any other applicable insurance.

0	fully met O	met O	partially met	0	not met	0	not applicable
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LAIP 2.2: All insurance coverage and explicitly those covering malpractice/liability/indemnity have an adequate coverage. The adequate and needed coverage may be defined and given by legal regulations, specifications of the insurer or can be estimated by research of closed laws cases where compensation was paid to (international) patients in the healthcare provider's country.

○ fully met ○ met ○ partially met ○ not met ○ not applicable

LAIP 2.3: As part of the healthcare provider's risk assessment risk of liability and likelihood of suits are differentiated.

0	fully met	° met	o partially met	O not met	o not applicable
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#### LAIP 3: Process for malpractice incidents including reporting

The healthcare provider has a policy and/or standard operating procedures on how to deal with malpractice incidents. A respective documentation and reporting system is implemented.

0	fully met	o met	o partially met	O not met	not applicable
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#### LAIP 4: Legal and illegal treatments

LAIP 4.1: The healthcare provider is aware and has a policy or similar process to address services that are illegal in the patient's home country but legal in the destination country.

C fully met	° met	o partially met	o not met	o not applicable
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LAIP 4.2: The healthcare provider clearly refrains from services that are illegal in the patient's home country and in the destination country.

○ fully met	t O partially met	o not met	<ul> <li>not applicable</li> </ul>
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#### LAIP 5: Prevention of fraud, corruption and bribery

LAIP 5.1: The healthcare provider has a policy in place describing the healthcare provider's approach and measures against fraud, corruption and bribery within the healthcare provider as well as in its relationships with subcontractors, suppliers, consultants and other external service providers.

The goals are to comply with safety and regulatory specifications, to increase patient and staff safety, to effectively use resources, and to assure equity and justice.

0	fully met	o met	o partially met	O not met	o not applicable
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## Glossary – Definitions and Abbreviations

### Temos Accreditation System

Access/accessible	Ability of patients/service users or potential patients/service users to obtain required or available services when needed within an appropriate time.
Accountability	Responsibility and requirement to answer for tasks or activities. This responsibility may not be delegated and should be transparent to all stakeholders.
Accreditation	Act of granting credit or recognition by an external evaluation organization of the achievement of accreditation standards, demonstrated through an independent external peer assessment of that organization's level of performance in relation to the standards.
A(C)LS	Advanced (Cardiac/Cardiovascular) Life Support
Adequate/appropriate	The degree to which something is suitable for a specific purpose. This may be that a service is consistent with a patient/service user's expressed requirements.
ADL	Activities of Daily Life
ALARA	As Low As Reasonably Achievable
APR	Accreditation Participation Requirements
AQ	(Temos) Annual Questionnaire
Assessment/re- assessment	Process by which the characteristics and needs of patients/service users, groups or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for services or action. A systematic evaluation process of collecting and analyzing data to determine the current, historical or projected compliance of an organization to a standard.
Assessor	External peer reviewer. Synonym for auditor, surveyor and similar.
Audit	Synonym: assessment
BAI	Billing and Accounting on International Level - TIHA standards chapter
Benchmarking	A technique in which an organization measures its performance against that of best in class companies, determines how those organizations achieved their performance levels and uses the information to improve its own performance. Subjects that can be benchmarked include strategies, operations and processes.
Benefit-cost analysis	An examination of the relationship between the monetary cost of implementing an improvement and the monetary value of the benefits achieved by the improvement, both within the same time period.
Best practice	A superior method or innovative practice that contributes to the improved performance of an organization, usually recognized as best by other peer organizations.
BLS	Basic Life Support
CCU	Coronary Care Unit
CDC	Centers for Disease Control and Prevention

Certification	Formal recognition of compliance with set standards/quality criteria validated by external evaluation.
Chart	A tool for organizing, summarizing and depicting data.
Checklist	A tool for ensuring that all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation.
CIRS	Critical Incident Reporting System
Client/customer/consumer	Individual or organization being served by another organization.
CME	Continuous Medical Education
Code of behavior (conduct)	Documented set of agreed principles and guidelines that is a guide for behaviors and informs all parties of responsibilities and expectations under the code.
СОМ	Committees - TIHA standards chapter
Community	Individuals, families, groups and organizations that interact with one another, cooperate in common activities, solve mutual concerns, usually in a geographic locality or environment.
Company culture	A system of values, beliefs and behaviors inherent in a company. To optimize business performance, top management must define and create the necessary culture. Similar to company strategy or Corporate Identity (CI)
Competence	An individual's knowledge and skills are appropriate to the services provided and assurance that the knowledge and skill levels are regularly evaluated.
Complaint	Expression of a problem, an issue, or dissatisfaction with services that may be verbal or in writing.
Complaint management	The system by which an organization deals with customer complaints.
Confidential/ confidentiality	Guaranteed limits on the use and distribution or information collected from individuals or organizations.
Conformity/non- conformity	Conformity is the ability of a process output to satisfy the requirements it is desired to meet. The output may be a product, service, document, record, etc., and the requirements are those that the company has decided are required for the output article. Conformity is when the output meets the requirements, and inversely, non-conformity is when the output fails to meet one or more requirements.
Continuous Quality Improvement	Systematic and continuous actions to lead to measurable improvement in health care services and patient safety.
Coordination	The process of working together effectively with collaboration among providers, organizations, teams and services in and outside the organization to avoid duplication, gaps, or breaks.
COPD	Chronic Obstructive Pulmonary Disease
Correction	When a nonconformity occurs, there are steps taken to correct the immediate problem. If a document is incorrect, an update is done on the document. If a drawing is wrong, the drawing is corrected. This addresses the immediate problem so that work can continue.
Corrective action	A solution meant to reduce or eliminate an identified problem.
Credential	Proof an individual's knowledge, skills, and competence and their compliance with specific requirements.

Criteria	Specific steps to be taken or activities to be done, to reach a decision or a standard.
Critical Incident Reporting System	A reporting system for the (anonymized) reporting of critical incidents and near misses.
Critical processes	Processes that present serious potential dangers to human life, health and the environment or the risk to lose significant sums of money or customers.
CRM	Customer Relationship Management
CSSD	Central Sterile Supply Department
CTG	Cardiotocography
Culture/cultural needs	A shared system of values, beliefs and behaviors. The design and delivery of services consistent with the cultural values of those who use them.
Customer satisfaction/feedback	Customer satisfaction is to what extent your customers perceive your product or service meets their requirements.
Data	Unorganized facts from which information can be generated.
DBS	Deep Brain Simulation
DDF	Documentation, Discharge and Follow-up - TIHA standards chapter
Demand	(Temos) Corrective action is required.
DICOM	Digital Imaging and Communications in Medicine
DLIS	Diagnostic, Laboratory and Imaging Services - TIHA standards chapter
EAIP	Ethical Aspects in International Patient Management - TIHA standards chapter
ECRI	Emergency Care Research Institute
ED	Emergency Department
Education	Systematic instruction and learning activities to develop or bring about change in knowledge, attitudes, values or skills.
EEG	Electroencephalography
Effect	The result of an action being taken.
Effective	The degree to which services, interventions or actions are provided in accordance with current best practice in order to meet goals and achieve optimal results.
	The degree to which resources are brought together to achieve desired results most cost effectively, with minimal waste, redundancy and effort.
Efficient	A comparison of the results achieved and the resources needed to achieve the results. A process can be effective, but if it takes too many resources to achieve the results, the process may not be considered efficient.
EFM	Electronic Fetal (Heart) Monitoring
EiMT	(Temos) Excellence in Medical Tourism
EMG	Electromyography
Ethics/ethical	Acknowledged set of principles which guide professional and moral conduct.
EU	European Union

Evaluation	Assessment of the degree of success in meeting the goals and expected results (outcomes) of the organization, services, programs or clients.
External evaluation organization	A recognized body that evaluates through independent peer assessment the performance of organizations in relation to quality standards for organizational functions.
Facilitator	Synonym for medical travel coordinator, agent, broker, etc.
Failure Analysis	Logical and systematic examination of equipment or a machine and/or its documentation to detect and analyze the causes, probabilities, and consequences of actual or potential failure with the goal of determining corrective actions or liability.
FDA	Food and Drug Administration
FMIS	Facilities Management Information System
FSIS	Facility Services, Infrastructure and Safety - TIHA standards chapter
GDPR	General Data Protection Regulation
GML	Governance, Management and Leadership in an International Patient- oriented Organization - TIHA standards chapter
GMP	Good Manufacturing Practice
Goals	Broad statements that describe the outcomes an organization is seeking and provide direction for day to day decisions and activities.
Governance	The function of determining the organization's direction, setting objectives and developing policy to guide the organization in achieving its mission, and monitoring the achievement of those objectives and the implementation of policy.
Governing body	Individuals, group or agency with ultimate authority and accountability for the overall strategic directions and modes of operation of the organization. Also known as the council, board, board of commissioners, etc.
Guidelines	Principles guiding or directing action.
НАССР	Hazard Analysis and Critical Control Points
HAI	Hospital-Acquired Infections
НАМ	High Alert Medication
Hazard Analysis and Critical Control Points	HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.
Health professionals	Medical, nursing or allied health professional staff that provide clinical treatment and care to patients/service users, having membership of the appropriate professional body and, where required, having completed and maintained registration or certification from a statutory authority.
Health Technology Assessment	The careful evaluation of medical technology including pharmaceutical products for evidence of its safety, efficacy, cost, cost effectiveness and ethical and legal implications
HIS	Hospital Information System
HIV	Human Immunodeficiency Virus
HRET	Human Resources (HR), Continuous Medical Education (CME) and Training - TIHA standards chapter

HR	Human Resources
HTA	Health Technology Assessment
HVAC	Heating, Ventilation, Air-Conditioning system
ICD	International Classification of Diseases
ICHP	Infection Control, Hygiene and Prevention - TIHA standards chapter
ICU	Intensive Care Unit
IDC	Independent Double Checks
IHI	Institute for Healthcare Improvement
Important To Quality (ITQ)	(Temos) Critical quality parameters important to quality of the process or service with a direct or indirect impact on quality and/or patient and staff safety.
Incidents	Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on patients/service users, clients, groups, staff, or the organization.
Indicator	Performance measurement tool that is used as a guide to monitor, evaluate, and improve the quality of services. Indicators relate to structure, process, and outcomes and are rate based, i.e. have a numerator and denominator so that they can be compared and benchmarked.
Information	Data that is organized, interpreted and used. Information may be in written form or other media such as: audio, video or photograph form.
Informed consent	Voluntary agreement or approval given by an individual.
Infrastructure	The physical surroundings required for a business such as buildings, utilities, process equipment, transportation services and IT systems.
IPD/IPU/IPO	International Patient Department/International Patient Unit/International Patient Office
IPM	International Patient Management - TIHA standards chapter
IPSG	International Patient Safety Goals - TIHA standards chapter
ISO	International Organization for Standardization
ISQua	International Society for Quality in Health Care
JCI	Joint Commission International
Key Performance Indicator	Quantifiable measures that reflect the critical success factors of an organization. Data to consistently measure and tack operations and performance to help serve patients, employees, and communities.
КРІ	Key Performance Indicator
LAIP	Legal Aspects in International Patient Management - TIHA standards chapter
LASA	Look-Alike, Sound-Alike drugs
Links	Connections, contacts, work partners and working relationships established with others.

Management	Setting targets or goals for the future through planning and budgeting, establishing processes for achieving those targets and allocating resources to accomplish those plans. Ensuring that plans are achieved by organizing, staffing, controlling and problem – solving.	
MCF	Medical Clearance Form	
Mission	A broad written statement in which the organization states what it does and why it exists. The mission sets apart one organization from another.	
MICU	Mobile Intensive Care Unit	
MRI	Magnetic Resonance Imaging	
MSDS	Material Safety Data Sheet	
MSE	Medical Services - TIHA standards chapter	
MTC	(Temos) Medical Travel Coordination	
NICU	Neonatal Intensive Care Unit	
NLS	Newborn Life Support	
NMS	Nursing and Midwife Services - TIHA standards chapter	
Nonconformity	Deviation from a TIHA standard. In the TIHA rating and scoring system nonconformities are classified as minor nonconformity leading to recommendations/potential for improvement or major nonconformity requiring corrective action stated as demand in the assessors' assessment report.	
Objective	A target that must be reached to achieve goals. It is the translation of the goals into specific, concrete terms against which results can be measured.	
OEI	Outcome, Effectiveness and Quality Improvement - TIHA standards chapter	
Operation/operational	The processes, actions and resources to achieve the goals and objectives of the organization.	
OR, OT	Operating Room or Operating Theater	
Organization	Comprises all sites/locations under the governance of, and accountable to, the governing body/owner(s).	
Orientation	The process by which staff become familiar with all aspects of the work environment and their responsibilities.	
OVF	(Temos) Onsite Validation Form	
PACS	Picture Archiving and Communication System	
PALS	Pediatric Advanced Life Support	
Patient safety	Prevention of errors and adverse effects to patients associated whit health care.	
РВМ	Patient Blood Management and Blood Bank - TIHA standards chapter	
PDCA cycle	Plan-Do-Check-Act is a conceptual cycle for implementing change which, when followed and repeated, would lead to repeated improvements in the process it was applied to.	
Performance evaluation	The continuous process by which a manager and a staff member review the staff member's performance, set performance goals, and evaluate progress towards these goals.	
PICU	Pediatric Intensive Care Unit	

PLS/PBLS	Pediatric (Basic) Life Support
Policy	A proposed or adopted course or principle of action. Documented statements that formalize the approach to tasks and concepts that are consistent with organizational objectives.
PPE	Personal Protective Equipment
PPM	Planned Preventive Maintenance
Preventive action	An action taken to reduce or eliminate the probability of specific undesirable events from happening in the future.
Procedure	Written sets of instructions conveying the approved and recommended steps for a particular act or series of acts.
Process	Series of interrelated activities and communications which accomplish services.
Provider	Organization or group which provides health care which can be primary care, community, acute, specialist, social services.
QiIDC	(Temos) Quality in International Dental Care
QiIEC	(Temos) Quality in International Eye Care
QiIMTC	(Temos) Quality in International Medical Travel Coordination
QiIPC	(Temos) Quality in International Patient Care
QilRehC	(Temos) Quality in International Rehab Care
QilRepC	(Temos) Quality in International Reproductive Care
QMS	Quality Management System
QMSV	Quality Management and System Validation - TIHA standards chapter
Qualified	Having the credentials for, being professionally and legally prepared and authorized to perform specific acts.
Quality	The degree of excellence, extent to which an organization meets clients' needs and exceeds their expectations.
Quality improvement	On–going response to quality assessment data about a service in ways that improve the processes by which services are provided to clients.
Quality policy/quality objectives	The quality policy comprises the overall goals, intentions and direction that the management of an organization has identified for quality. Quality objectives are specific goals designed to support the overall quality policy and are specified for relevant employees and departments throughout the organization.
Recommendation	(Temos) There is potential for improvement; the organization is advised to implement, add or change for the better.
Reliability	Extent to which results are consistent through repeated measures by different measurers, or at different times by the same measurer, when what is measured has not changed in the interval between measurements.
Requirement	Constraints, demands, necessities, needs, or parameters that must be met or satisfied.
Research	Contribution to an existing body of knowledge through investigation, aimed at the discovery and interpretation of facts.
Results (outcomes)	The consequence of a service or intervention.
Rights	Something that can be claimed as justly, fairly, legally, or morally one's own. A formal description of the services that clients can expect and demand from an organization.

RIS	Radiology Information System
Risk	Chance or possibility of danger, loss or injury. This can relate to the health and well-being of staff and the public, property, reputation, environment, organizational functioning, financial stability, market share and other things of value. The result of uncertainty, or the chance that an event will occur.
Risk management	A systematic process of identifying, assessing and taking action to prevent or manage clinical, administrative, property and occupational health and safety risks in the organization.
Risk management framework	A set of components that provide the foundations and organizational arrangements for designing, implementing, monitoring, reviewing and continually improving risk management throughout the organization. The framework should be embedded within the organization's overall strategic and operational policies and practices.
ROS	Reverse Osmosis Systems
RT-CGM	Real Time Continuous Glucose Monitoring
Safety	The degree to which the potential risk and unintended results are avoided or minimized.
SALAD	Sound Alike / Look Alike Drugs. Some proprietary (brand name) and non-proprietary names (generic name) sound or appear to be similar to other drugs when written or spoken. These confusing drug names are one of the main causes of medication errors. These errors may cause harm or even death to patients.
SAS	Support and Ancillary Services - TIHA standards chapter
Scope	The range and type of services offered and any conditions or limits to service coverage.
SCS	Spinal Cord Simulation
Services	Products of the organization delivered to patients/service users, clients, or units of the organization that deliver products.
SHS	Sustainability in Healthcare Settings - TIHA standards chapter
SOP	Standard Operating Procedure A set of step-by-step instructions compiled by an organization to help its staff carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with regulations.
Staff	Employees of the organization.
Stakeholder	Individuals, organizations or groups that have an interest or share in services.
Standard	A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. A desired and achievable level of performance against which actual performance is measured.
Strategic plan	A formalized plan that establishes the organization's overall goals, and that seeks to position the organization in terms of its environment.
ТААВ	Temos Assessors' Advisory Board

ТАС	Temos Accreditation Chart
TAS	Temos Accreditation Standards
TCR	Temos Criteria Requirements
TIC	Temos Information Chart
TIHA	Temos International Healthcare Accreditation
TLD	Thermoluminescent Dosimeter
том	Total Quality Management A holistic approach to long-term success that views continuous improvement in all aspects of an organization as a process and not as a short-term goal. It aims to radically transform the organization through progressive changes in the attitudes, practices, structures, and systems.
UPS	Uninterrupted Power Supply
Validity	The relationship of the data obtained to the purpose for which it accomplishes, or measures what it seeks to measure.
WHO	World Health Organization
Work instructions	A work instruction describes how to perform a task.

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