

Sleep Medicine

Ethical and Legislative Considerations

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Agenda

1. Relevant Ethical Principles.
2. Sale of Medical Devices.
3. Management of Patients.
4. Telemedicine.
5. International Perspectives.
6. Focus Points.



Ethical Principles and Rules

- **Perverse Incentives**
 - Improper financial gain or other valuable consideration
- **Fee Sharing**
 - May not share fees with any other entity/practitioner who has not taken a commensurate part in the service rendered.
- **Preferential usage or Prescriptions**
 - No engagement in or advocacy of the preferential use of any health establishment or medical device which provides improper financial gain



Ethical Principles and Rules

- Sale of medical devices – Rule 23
 - No participation in the manufacture sale, advertising or promotion of any medical device
 - Advocacy and use of medical device only where it is clinically appropriate or most cost-effective
- Best Interests of the patient
- Informed Consent
- Confidentiality



Medical Device Regulation

- Presently no regulations governing the sale and use of medical devices in South Africa.
- Draft Regulations in place – yet to be finalised
- The industry self-regulates.
- SAMED
 - The SAMED Code of Business Practices
- The Marketing Code Authority
 - South African Code of Practice for the Marketing of Health Products
- Both entities are voluntary and can only enforce their codes on member entities



Management of Patients

- The practitioner is ultimately responsible for the management and care of their patient.
- Where any function is out-sourced, the responsibility and liability remains with the practitioner.
- Interpretations of results and reports received from third party service providers do not remove liability of the practitioner.
- Permissible to receive reports from other practitioners and prescribe accordingly– Rule 23(5)



Telemedicine

- Condemned by the HPCSA
 - Face to Face to face consultation
 - Physical examination required
 - Informed consent and confidentiality issues.
- Shift in Focus – geographical considerations, scarcity of skills (specialist)
- Department of Health
 - A Telemedicine Strategy for South Africa 2010-2015



Telemedicine

- “General Ethical Guidelines for Good Practice in Telemedicine” – HPCSA Booklet 17
 - Asynchronous and Synchronous transmission of patient data
 - Competence, Registration and Authorisation
 - Consulting and servicing practitioners
 - Ethical obligations and standards of care remain the same as in “face-to-face” consults
 - Assumption of Primary Responsibility – WMA recommendations on consulting and servicing practitioners
 - Routine, Specialist and Emergency consultations
 - Quality, security and safety of patient information and records
- Paradigm shift to acceptance of telemedicine



International Perspective

American Academy of Sleep Medicine recommendations:

- Clinical care standards of telemedicine services should mirror live office visits
- Clinical judgment – scope and extent of telemedicine services
- Reimbursement should be comparable to live interactions
- Telemedicine should be part of a co-ordinated model of healthcare delivery
- Appropriate technical standards should be upheld – HIPAA
- Improvement of utility of telemedicine should be explored
- Quality assurance processes should be in place
- Adherence to strict professional and ethical standards
- Financial transparency in respect of payment arrangements
- Continued research is required



Focus Points

- The medico-legal environment becoming more litigious
- Adherence to legislation, ethics and industry codes ever more important.
- Regulatory environment is in a state of flux.
- Active engagement required by interested parties to contribute to changes to policy and legislation.
- Financial considerations must not diffuse the focus on patient care
- Medical Device utilisation is essential, but only a component of holistic patientcare and management.



Thank You

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