



The MA Board of Registration in Medicine

Written Informed Consent: What Every Patient Doesn't Know But Should Ask

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243 CMR Chapter 2.00 Amendments Licensing and the Practice of Medicine

Procedural History:

- Amendments approved by the Board in 2016
- Public Comment
- Reviewed Amendments Post Comment
- Voted by the Board July 17, 2019
- Promulgated August 9, 2019

What was our goal in amending 243
CMR Chapter 2.00, specifically
informed consent?

243 CMR 2.07 (26) Informed Consent: Sections

- When Informed Consent is Necessary
- Duty of Attending Physician/Primary Operator
- Informed Consent Shall Be Clear and Detailed
- Patients Medical Records Must Reflect Who Will Participate in the Procedure
- Patients Medical Record Must Reflect Any Absence of Attending Physician/Primary Operator
- Written Policy on Written Informed Consent

When Informed Consent Is Necessary

- The regulation did not change the circumstances requiring informed consent
- If you were required to obtain informed consent before the procedure, you are now required to obtain it in writing
- Standard regarding informed consent has been the same since 1982
- FAQ's

Duty of Attending Physician/Primary Operator

- Responsibility of the attending physician/primary operator to obtain written informed consent
- Discuss significant medical information
- FAQ's

Informed Consent Shall Be Clear and Detailed

- Shall be documented in writing
- Sufficient clarity
- Identify attending physician/primary operator
- Signatures
- FAQ's

Patient's Medical Record Must Reflect Who Will Participate in the Procedure

- Prior to the procedure
- Including names of all physician extenders
- Residents and Fellows
- FAQ's

Patient's Medical Record Must Reflect Any Absence of Attending Physician/Primary Operator

- Who documents
- Absence from procedure
- Who was attending physician primary operator during the absence
- FAQ's

Written Policy on Written Informed Consent

- Designation of persons responsible for obtaining written informed consent
- How will it be documented
- Designation of appropriate persons from whom consent may be obtained

A photograph of a large group of people in a meeting room. Many individuals are slumped over their desks, some with their heads resting on their hands, suggesting a lack of attention or interest. The room has large windows with blinds in the background. The text "QUESTIONS??" is overlaid in a large, yellow, serif font across the center of the image.

QUESTIONS??