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3 **Title: Mandatory Electrophysiologic Testing for Patients Taking**
4 **Vigabatrin (Sabril™)**
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6 **Introduced by: Domenic R. Federico, MD, for the Kent County Delegation**
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8 **Original Author: Patrick J. Droste, MD**
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10 **Referred to: Reference Committee E**
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12 **House Action: Adopted as Amended**
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15 **Whereas, Vigabatrin has been safely used for the control of seizures for**
16 **the last 15 years in the United States, and**
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18 **Whereas, Vigabatrin has been recently approved by the U. S. Food and**
19 **Drug Administration (FDA), and**
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21 **Whereas, according to the Risk Evaluation and Mitigation Strategy**
22 **program requirements mandated by the FDA, vision testing is required every**
23 **three months in order for patients to continue receiving Vigabatrin, and**
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25 **Whereas, mandatory ophthalmologic testing also includes**
26 **electroretinography ocular coherence tomography and visual evoke response**
27 **testing, and**
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29 **Whereas, it is very difficult to perform electrophysiologic testing,**
30 **including visual evoke response testing, electroretinographic testing, and**
31 **ophthalmic coherence tomography testing on children without sedation or**
32 **general anesthesia, and**
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34 **Whereas, there is no clinical evidence that any of the tests are shown to**
35 **prevent any possible visual loss associated with the use of Vigabatrin, and**
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37 **Whereas, risk of new and worsening vision loss continues as long as**
38 **Vigabatrin is used and possibly after discontinuing its use, and**
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40 **Whereas, periodic vision testing is required for patients taking**
41 **Vigabatrin/Sabril™, but cannot reliably prevent vision damage; therefore be it**
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43 **RESOLVED: That the Michigan Delegation to the AMA ask the AMA to**
44 **oppose the FDA's rigid schedule of vision testing for patients with Vigabatrin,**
45 **but to favor instead a recommendation that physicians prescribing Vigabatrin**
46 **arrange follow-up testing of vision as clinically appropriate.**
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49 **WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**