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3 **Title: Addressing Drug Shortages**
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5 **Introduced by: James Szocik, MD, for the Washtenaw County Delegation**
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7 **Original Author: James Szocik, MD**
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9 **Referred to: Reference Committee B**
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11 **House Action: Adopted**
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14 **Whereas, drug shortages have increased over the years from 2005 to**
15 **present¹, and**

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17 **Whereas, the Food and Drug Administration is tracking these shortages²,**
18 **and**

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20 **Whereas, the Food and Drug Administration will not address economic**
21 **issues as these are beyond its scope³, and**

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23 **Whereas, the economic issues may be the underlying etiology for many**
24 **of the drug shortages due to the influence of Group Purchasing Organizations**
25 **(GPOs) and the lack of significant enforceable “failure to supply” clauses, and**

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27 **Whereas, inclusion of such clauses in contractual arrangements with**
28 **either GPOs or pharmaceutical manufacturers would provide an incentive for**
29 **both to ensure a consistent supply of critical medications; therefore be it**

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31 **RESOLVED: That our AMA educate its members and the public as to the**
32 **economic and health aspects of drug shortages via material on the web; and be**
33 **it further**

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35 **RESOLVED: That MSMS and the AMA work to draft example economic**
36 **contractual solutions to the drug shortages; such as “failure to supply “clauses**
37 **that are legally enforceable with the aim of decreasing drug shortages by**
38 **increasing supply, either by encouraging Group Purchasing Organizations to**
39 **buy more than is needed and stockpile excess drug (and take the financial risk)**
40 **or encouraging the manufacturer to develop excess capacity to meet sudden**
41 **unanticipated shortages (and take the financial risk); and be it further**

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43 **RESOLVED: That our AMA work with the Food and Drug Administration**
44 **in its continued efforts to decrease drug shortages by tracking the impact of**
45 **any “failure to supply” clauses on drug costs, drug supply, and drug shortages;**
46 **and be it further**

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48 **RESOLVED: That, in the event that legal and contractual solutions fail as**
49 **evidenced by continued or worsening drug shortages as tracked by the Food**

50 and Drug Administration (FDA), that MSMS and the AMA work with legislators
51 to propose laws addressing the economics of the drug shortage that may act as
52 restraints on trade well outside the jurisdiction of the FDA, such as mandating
53 multiple supply chains, stockpiling of drugs, or other means to decrease
54 shortages; and be it further

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56 **RESOLVED:** That our AMA advocate that any legislation that addresses
57 the economics of the drug shortage, such as mandating multiple supply chains,
58 stockpiling of drugs, or other means to decrease shortages include both a
59 sunset provision and a monitoring period to assure their effectiveness.

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62 **WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE**

¹ <http://aspe.hhs.gov/sp/reports/2011/drugshortages/ib.shtml>

² <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm>

³ <http://oversight.house.gov/wp-content/uploads/2012/06/6-15-2012-Report-FDAs-Contribution-to-the-Drug-Shortage-Crisis.pdf>