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Title Repeal Safe Harbor Provisions
Introduced by: James Szocik, MD, for the Washtenaw County Delegation
Original Author: James Szocik, MD
Referred To:
House Action:

Whereas, group purchasing organizations (GPO) and pharmacy benefits managers (PBM) act as middlemen between producers of drugs and supplies and the consumers, hospitals and patients, and

Whereas, GPO and PBM propose to add value to the consumers by negotiating contracts, but in reality they extract "rent," limit innovation distort prices (IV saline is sold at below cost because it is "coupled" with other purchases), and contribute to drug shortage, and

Whereas, GPO and PBM further offer "rebates" to hospital systems and major consumers that would otherwise be categorized as "bribes" or "kick-backs" and are only allowed under special "safe harbor provisions" of U.S. law, and

Whereas, this results in increased costs for the end consumer, and

Whereas, the previous Administration supported and was working on eliminating these safe harbors, the current Administration has suspended all implementation of such changes; therefore be it

RESOLVED: That MSMS advocate for the repeal of the "Safe Harbors" under 42 CFR 1001.952(j) , 42 U.S.C. 1320a-7b(b)(3)(C) and any other state or federal statutes that may apply and support the substitution of rebates directly to the consumer and the public; and be it further

RESOLVED: That the Michigan Delegation to the American Medical Association (AMA) urge our AMA to advocate for the repeal of the "Safe Harbors" under 42 CFR 1001.952(j) , 42 U.S.C. 1320a-7b(b)(3)(C) and any other state or federal statutes that may apply and support the substitution of rebates directly to the consumer and the public.

WAYS AND MEANS COMMITTEE FISCAL NOTE: Resolutions requesting governmental advocacy - \$25,000+

STATEMENT OF URGENCY: In November 2020, the HHS OIG finalized its previously abandoned 2019 proposal to exclude certain rebates paid by drug manufacturers from the discount safe harbor to the federal anti-kickback statute. The rule is expected to go into effect in January 2021.

Relevant MSMS Policy:

None

Relevant AMA Policy:

None

Sources:

1. <https://www.modernhealthcare.com/article/20190119/NEWS/190119924/are-gpos-pbms-part-of-the-drug-cost-problem-or-the-solution>
2. <https://www.masimo.com/company/news/media-room/antitrust-litigation/>
3. <https://khn.org/wp-content/uploads/sites/2/2016/10/pipelinetoprofits.pdf>
4. <https://www.gao.gov/assets/590/589778.pdf>
5. <https://jamanetwork.com/journals/jama/fullarticle/2708613>
6. <https://www.jdsupra.com/legalnews/trump-administration-revives-rebate-84255/>