RESOLUTION #7—2022 Regular Annual Session

Submitted by Board of Directors

NEW POLICY ON ADVERSE EVENT REPORTING

RESOLVED that the American Veterinary Medical Association (AVMA) House of Delegates adopt the new policy on Adverse Event Reporting as noted in <u>Attachment 1</u>, which will supersede the current policies on <u>Adverse Event Reporting</u> and on <u>Vaccinovigilance</u>.

Statement about the Resolution

The Council on Biologic and Therapeutic Agents (COBTA) reviewed the policies on Adverse Event Reporting and Vaccinovigilance. The intent is to:

- Create one policy that addresses adverse event reporting for both pharmaceuticals and vaccines (rather than having separate policies for each product);
- Define the terms "adverse event" and "veterinary pharmacovigilance" as they pertain to any veterinary product;
- Revise language indicating that adverse event reporting systems are a high priority not only for USDA, and include FDA and EPA on the list of regulatory agencies that maintain adverse event reporting systems; and
- Encourage veterinary adverse event reporting.

Financial Impact: None

	Board of Directors	House Advisory Committee	Reference Committee #2	House of Delegates
Recommend	X	X	X	X
Approval				
Recommend				
Disapproval				
Recommend				
Referral to				
No				
Recommendation				
Recommend				
Postpone				
Indefinitely				

(use this space for additional narrative, if needed)