RESOLUTION NUMBER:  32 and 36 Combined       APPROVED AS AMENDED

SOURCE:       COMMITTEE ON PHARMACEUTICALS
               COMMITTEE ON ANIMAL WELFARE

SUBJECT MATTER:   CONTROLLED SUBSTANCES ACT REGULATIONS
                  APPLYING TO DRUG ENFORCEMENT ADMINISTRATION
                  REGISTRANTS ACTING REMOTELY FROM
                  REGISTRANT’S PRINCIPAL PLACE OF BUSINESS

BACKGROUND INFORMATION:

Many pharmaceuticals, which are used for a variety of indications, including sedation, anesthesia, pain management, and euthanasia, are classified as controlled substances because of their potential for misuse or abuse. The purchase, use, and disposal of these pharmaceuticals are controlled by the United States Drug Enforcement Administration (DEA) as directed by the United States Department of Justice and authorized by the Controlled Substances Act (CSA). Registrations are issued to qualified applicants for use of specified classes of these pharmaceuticals.

United States Code (U.S.C.) Title 21 Section 822 (a) and (e) of the CSA outline who is required to register with the DEA to manufacture, distribute, or dispense controlled substances. Per 21 U.S.C. § 822 (e), a separate registration is required at each principal place of business or professional practice where the applicant dispenses controlled substances. This means it is illegal to transport, administer, or dispense controlled substances outside of the premises listed on the applicant’s registration. Historically, the DEA has applied regulatory discretion to enforcement of this limitation, allowing registrants to use controlled substances at remote locations as medical needs indicate. During the past six months, some DEA field offices have indicated an interest in scrutinizing or enforcing the regulations. The potential impacts of such enforcement on animal welfare are serious because it may preclude the use of controlled drugs (for which there may be no satisfactory substitute) to relieve animal suffering. Because DEA contends that the current law does not permit practitioner registrants to dispense controlled substances in mobile or ambulatory practice in a realistic or practical way, it is impossible to provide appropriate care within the confines of the law in the event that animals need treatment at a remote location.

In 2010, combined United States Animal Health Association (USAHA) resolutions 12 and 25 (approved as resolution 12) attempted to address the corollary issue of veterinarians who deliver services in states other than those in which they have physical principal places of business (e.g., veterinarians in ambulatory or travelling specialty/special-interest services).
practices, who are on or near state borders and hold veterinary licenses in more than one
state; practitioners acting as part of emergency service teams; practitioners participating in
programs that provide services to underserved populations). That resolution asked the
Attorney General to exercise authority granted by the Controlled Substances Act of 1970,
21 U.S.C. § 822 (d), to promulgate regulations that would waive the requirement for
veterinarians in ambulatory practices to have a separate United States Department of
Justice Drug Enforcement Administration registration in each state in which they are
licensed or authorized to practice.

Two important points have been made clear from the DEA’s response to the 2010 USAHA
resolution, as well as its response to requests from stakeholders to modify regulatory
requirements and allow registrants to transport controlled substances to locations remote
from registrants’ principal place of business (which may be necessary either within a given
state or across state lines). The first is that this is a complex issue affecting many
dispensers including, but not limited to, veterinarians. The second is that the authority
accorded by 21 U.S.C. § 822 to the Department of Justice is insufficient to allow concerns
to be resolved through a regulatory process—statutory change is required.

RESOLUTION:

The United States Animal Health Association urges Congress to amend the Controlled
Substances Act to provide a legal means by which the United States Department of
Justice, Drug Enforcement Administration registrants or authorized agents may
appropriately transport and utilize controlled substances when acting in the normal course
of business or employment pertaining to the treatment of animals (domestic and wildlife)
in locations outside of the principal place of business listed on their registration.