



**ASSOCIATION OF
AMERICAN
MEDICAL COLLEGES**

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June 10, 2003

Docket No. 97-033-1
Regulatory Analysis and Development, PPD
APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Animal Welfare, Medical Records

The Association of American Medical Colleges welcomes the opportunity to comment on Docket No. 97-033-1, a proposed rule that would require research facilities, dealers, and exhibitors to maintain medical records as part of their program of adequate veterinary care.

The AAMC represents the nation's 125 accredited medical schools, nearly 400 major teaching hospitals, more than 105,000 faculty in 96 professional and scientific societies, and the nation's 66,000 medical students and 97,000 residents. More than half of the extramural research funding awarded by the National Institutes of Health goes to medical schools and their affiliated teaching hospitals. Much of this research involves the use of laboratory animals. As such, the Association has a long history of involvement in legislative and regulatory issues concerning the use of animals in research and has a strong commitment to the humane care and treatment of laboratory animals.

We commend APHIS for using the formal rule-making process to offer the public and regulated community an opportunity to comment on the proposed rule. Too often in the past, the Department has used administratively issued Policies to implement new requirements and, thus, not make them subject to formal rule-making and comment procedures. Thus we welcome the use of the formal rule-making process.

The AAMC has carefully reviewed the detailed and thoughtful comments submitted by the National Association for Biomedical Research (NABR) and the American Physiological Society (APS). We endorse both NABR's and the APS's comments and call them to your attention.

Like our colleagues, the AAMC supports the proposition that maintaining appropriate medical records is an important component in documenting adequate veterinary care. However, we find the proposed rule to be overly prescriptive and inappropriate because it seeks to regulate many areas that are rightfully within the scope of the professional judgment of the attending veterinarian. We believe APHIS is proposing an expansive system of animal health records and has seriously underestimated the amount of time that will be needed and the volume of paperwork that it will generate. Moreover, some of the information APHIS proposes to require is superfluous to its stated goals of ensuring adequate veterinary care in the research environment. We share APS's view that, "The spirit of the proposed record-keeping requirements may be suitable for a veterinary clinic but not for a research

setting. Some provisions, such as the inclusion of a prognosis, call for a level of detail that might seem excessive even in human medicine.”

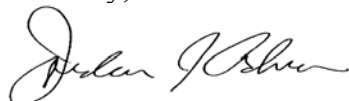
Although we share all the concerns detailed in the NABR and APS comments, we would like to highlight a few particularly egregious sections of the proposed regulation:

- Conditions created by or related to the design of a research protocol (induced disease) are not necessarily included in an individual animal’s health record. Record keeping for this set of conditions often is maintained as part of the research record. APHIS should include language in a new proposed rule exempting from the medical records requirements the observation, examination and treatment of induced disease covered under an approved protocol. In some cases maintaining medical records may be warranted, but in all instances the decision should rest with the attending veterinarian under the program of adequate veterinary care reviewed by the IACUC.
- The background section of the proposal contains a requirement that medical records include “any known drug sensitivities of the animals.” Other than some recognized species-specific drug idiosyncrasies, there is no scientific basis for evaluating drug sensitivities in laboratory animals. This language should be deleted in its entirety during promulgation of any final rule.
- The proposed rule states that medical records should include, “The type and chronology of treatment procedures performed, the context of the problem to which the treatment procedures pertain, and the identification of the medication used, the date given, dosage, route of administration, frequency and duration of treatment.” Providing “the context of the problem to which the treatment procedures pertain” will be extraordinarily burdensome and of no clear benefit to the goal of humane care. As our APS colleagues note, “The only justification for generating such records is to enable APHIS VMOs [veterinary medical officers] to review veterinary decisions after the fact.” This language should be deleted.

In summary, we believe that if the current proposal were promulgated without major revision, veterinarians and research institutions will be severely burdened with unnecessary work, animals will undergo unnecessary diagnostic procedures, and the system will be subject to unnecessary paperwork. We join NABR in urging “APHIS to commence a second round of notice and comment and reissue this proposal based upon the comments the agency receives in response to the current proposal.”

The AAMC appreciates the opportunity to comment on this proposal.

Sincerely,



Jordan J. Cohen, M.D

CC: OMB Office of Information and Regulatory Affairs