

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; (4) the names of all vaccines administered and the dates of vaccination; and (5) the dates and results of all screening, routine, or other required or recommended tests.

Amending the regulations to specifically include requirements for maintaining medical records would necessitate changes to the provisions of the regulations regarding recordkeeping requirements for research facilities, dealers, and exhibitors. Section 2.35 pertains to the recordkeeping requirements for research facilities, and paragraph (f) of that section stipulates that records and reports must be maintained for at least 3 years. We would amend the recordkeeping requirements for research facilities in § 2.35(f) to require that medical records be kept for 1 year after the disposition of the animals and that one copy of those records be provided to subsequent owners of the animals or to any person to whom the animals are consigned. The retention period for all other records and reports would continue to be 3 years.

We would amend § 2.75, regarding recordkeeping by dealers and exhibitors, by adding a new paragraph (b)(4) requiring that one copy of the medical records be provided to subsequent owners of the animals or to any other person to whom the animals are consigned. Because § 2.80 currently contains a requirement that dealers and exhibitors, among others, retain records for 1 year after the disposition of the animals, we would not need to provide a specific retention period for medical records.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This proposed rule would amend the Animal Welfare Act regulations to require that research facilities, dealers, and exhibitors maintain medical records as part of their program of adequate veterinary care. Currently, the maintenance of medical records is not specifically listed as one of the elements of a program of adequate veterinary care. However, we believe that requiring research facilities, dealers, and exhibitors to maintain medical records

would help ensure that animals receive adequate veterinary care. In addition, these records would provide a basis for APHIS to better assess the veterinary care programs of research facilities, dealers, and exhibitors.

In fiscal year 2000, there were 8,773 facilities of all sizes licensed or registered under the Act, including 4,612 dealers; 2,508 exhibitors; and 1,265 research facilities. Most research facilities are large relative to other regulated entities, and the average number of animals per research facility in fiscal year 2000 was 1,027.<sup>1</sup> This rule would affect those facilities that provide veterinary care.

In 1997, there were 10,045 U.S. farms in North American Industry Classification System (NAICS) category 11299 (All Other Animal Production, which includes dog and cat breeders/dealers), and the average annual sales per farm for that year was \$105,624, well below the U.S. Small Business Administration's (SBA) small entity threshold of \$750,000. In addition, in 1997, there were 4,607 U.S. firms in NAICS 541710 (Research and Development in the Physical, Engineering, and Life Sciences, which includes research facilities) that operated for the full year, and 99 percent of those firms had fewer than 500 employees, which is the SBA's small entity threshold for firms in NAICS 541710. In 1997, there were 498 firms in NAICS 711190 (Other Performing Arts Companies, which includes circus exhibitors) that operated for the full year, and 99 percent of those firms had less than \$5 million in sales that year, which is the SBA's small entity threshold for firms in NAICS 711190.

APHIS does not anticipate a great increase in burden to regulated entities. Almost all research facilities and more than 75 percent of other regulated facilities already comply with these proposed minimum standards for medical records. However, there may be a few entities that would need to improve the recordkeeping already in place, thus increasing their burden at least temporarily. We anticipate that the costs associated with any increase in burden would be minimal and would be limited primarily to the salary costs for the employee or employees responsible for assembling the documentation necessary to establish a medical record

that contains the information described in this proposed rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### **Executive Order 12988**

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

#### **Paperwork Reduction Act**

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 97-033-1. Please send a copy of your comments to: (1) Docket No. 97-033-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would amend the Animal Welfare Act regulations by requiring research facilities, dealers, and exhibitors to maintain medical records as part of their program of adequate veterinary care. We would require medical records to include: (1) The identity of the animal (with the exception that routine husbandry, such as vaccinations, preventive medical procedures, or treatments, performed on all animals in a group (or herd) may be

<sup>1</sup> See APHIS' Animal Welfare Enforcement Report for Fiscal Year 2000, available on the Internet at <http://www.aphis.usda.gov/ac/publications.html>. The average of 1,027 animals per research facility is based on 1,265 total facilities (1,231 active facilities and 34 inactive facilities).