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RULE PROPOSALS

AGRICULTURE

DIVISION OF ANIMAL HEALTH

40 N.J.R. 6257(a)

Proposed Amendment: N.J.A.C. 2:10-1.2

[Click here to view Interested Persons Statement](#)

Laboratory Services

Authorized By: State Board of Agriculture and Charles M. Kuperus, Secretary.

Authority: N.J.S.A. 4:5-2.1.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2008-367.

Submit written comments by January 2, 2009 to:

Dr. Nancy E. Halpern
NJDA/Division of Animal Health
P.O. Box 330
Trenton, NJ 08625

The agency proposal follows:

Summary

The State Board of Agriculture and the Department of Agriculture are proposing amendments to the fee schedule for veterinary diagnostic services pursuant to N.J.S.A. 4:5-2.1. The schedule of fees is to defray the costs of animal disease diagnostic and testing services. The State Board of Agriculture and Department of Agriculture have reviewed the proposed amendments and find these amendments to be necessary, reasonable and adequate, efficient, understandable, and responsive to the purpose for which they are promulgated. Adoption of these amendments is necessary to provide animal owners with animal disease diagnostics and defray the costs incurred by the Department in providing these services.

The collection of reasonable fees for animal disease diagnostic and testing services by the Department of Agriculture allows the Department to recover the costs incurred for materials, equipment, test kits, reagents, and associated personnel expenses for these testing services. The amendments are necessary to allow for the revision of user fees for veterinary diagnostic services to reflect changes in operating costs and changes in the method used to calculate Departmental costs. Additional user fees have been added to cover the costs of additional veterinary diagnostic services. There is a reduction of fees proposed, in some cases, as necessary to encourage animal owners to make use of the available services offered by the Department. In addition, certain user fees calculated for tests performed in groups have been proposed to offer diagnostic and economic benefits by providing a lower cost option when certain diagnostic tests are reorganized in a group related to the type of service.

The proposed amendments will not change the ability to allow for the testing and test cost reimbursement of new diseases and new testing formats as they emerge and are developed. The fees collected are held separate and apart from all other funds of the State in a non-lapsing revolving fund for annual appropriation to provide continuous support for the laboratory services.

The amendments are with regard to laboratory fees for services offered. In addition, the following specific amendments are proposed:

N.J.A.C. 2:10-1.2(b) adds a test, *Leptospira* microagglutination (MAT) and amends charges for bacteriology isolation and identification tests.

N.J.A.C. 2:10-1.2(c) eliminates species disease specific test techniques previously listed because they are included in the general listing of the test technique and it could be misleading to list only a few IFA and ELISA when there are many diseases. The changes in this subsection are also amended for virology identification tests. The fee for the Johne's ELISA test is listed separately and remains low because it is part of a program to encourage producers to participate in this program.

N.J.A.C. 2:10-1.2(d) eliminates listing of disease specific tests previously listed because they are included under the general test reference and it could be misleading to list only a few AGID when used for many diseases. The section also amends the fees that are restructured through grouping and amended charges for the ELISA serology testing (except for Johne's ELISA testing noted above).

N.J.A.C. 2:10-1.2(e) sets forth the amended charges for pathology services that now include necropsy of poultry (up to five birds) and additional detail including fees related to disposals and charges for field necropsy, histology, and sample collection. Procedures that are no longer separately listed and are no longer associated with separate lab fees are necropsy only, necropsy histopathology only, necropsy with infectious disease procedures, necropsy with all procedures and histology per tissue (biopsies). The same services are still being offered; however, in place of these separately listed procedures and associated separate fees, the procedures are now grouped in a package with a fee that will provide a more economical service than separate fees for each test. The procedures that are grouped together (histology, aerobic culture and fecal) are broad in scope and cover the most common causes of diseases in animals caused by parasites or bacterial infections. The fees for those procedures, which must be performed in the field are grouped based on tissue samples tested. The fees for these procedures reflect the additional resources required to perform these services in the field. Disposal of carcass fees are also necessary to address costs incurred by the lab for this service.

N.J.A.C. 2:10-1.2(f) sets forth amended (reduced) charges for battery testing based on clinical expression of diseases for certain species. (For example, the clinical expression may be through respiratory problems, abortions or neurologic problems.) Veterinarians request laboratory testing based on the clinical signs of the animals they are treating and such signs may be caused by any number of disease agents. Battery testing has been established by clinical symptom to rule out various disease agents that may cause such symptoms. These battery tests are [page=6258] based on serology and have been established to facilitate the most economic but accurate diagnostic tools. Individual costs for each included test, if done separately (and also included in the technique section of virology) are as follows: Serum

neutralization (SN) test is \$ 15.00; IgM antibody capture ELISA test is \$ 20.00; IgG antibody capture ELISA test is \$ 20.00; and histology (HI) serum titer is \$ 25.00. At the end of this fee schedule, the tests are formatted to group together species panels and to group together some procedures that are performed in both field and laboratory settings.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The prevention and control of disease by State regulatory programs is necessary to prevent and/or eliminate disease from the New Jersey livestock population, protecting the economic viability of the animal health industry, as well as the health of the livestock and other animals potentially susceptible to these diseases, including humans. Lack of Federal and State funds has resulted in user fees for services by the United States Department of Agriculture, National Veterinary Services Laboratory (NVSL) and other state laboratories across the U.S. Whereas, the New Jersey Department of Agriculture is now charged for tests and materials previously supplied free of charge by NVSL, the Department must recover these incurred expenses in order to maintain operation. Due to the lack of State appropriations and increasing expenses (for example, NVSL), the New Jersey Department of Agriculture has found it necessary to collect user fees for Department laboratory expenses incurred for livestock disease diagnostic and testing services. With continued implementation of these user fees, veterinarians who elect to use the Department laboratory services for routine diagnostic tests or voluntary control programs will be affected. In some areas, fees are being reduced by grouping procedures together. Without implementation of these fees for service, the Department will no longer be able to provide either routine or elective diagnostic testing and services for the livestock. Users of these services will have to find alternative laboratory services, all of which will include fees for service charges.

Livestock owners and veterinarians that use diagnostic laboratory services other than the New Jersey Department of Agriculture currently pay user fees. The amendments involving user fees by the Department are not expected to cause a negative reaction by current laboratory users. Livestock owners and veterinarians are aware that fees for service charges are a standard in the animal health industry.

The proposed amendments allow for collection of reasonable user fees to offset Department expenses and allow the Department to continue to offer animal diagnostic testing services. Therefore, the proposed amendments will have a positive social impact on the citizens of the State of New Jersey.

Economic Impact

New Jersey livestock owners who use the services of the Department of Agriculture's animal health diagnostic laboratories will be affected economically by the proposed amendments. However, in some cases the costs are proposed for reduction by grouping and livestock owners continue to have the option to utilize the services of private laboratories. In addition, the amendments provide a lower cost option when certain diagnostic tests are reorganized in a group related to the type of service.

The proposed fees reflect changes in the cost of supplies, as well as the cost of the professional performing the service. While most testing fees have increased as result of increased costs, some of the fees for indirect fluorescent antibody tests have been reduced. As a result of concerns about emerging diseases and bioterrorism, the lab fees include costs of field investigations, as well as small animal pathology services. While some of this testing will be subsidized by Federal agencies and regulatory tests, mandated by the Department for the purpose of diagnosing or controlling reportable diseases in New Jersey livestock, will be supported through the State appropriation system when available, the Department anticipates increased utilization of laboratory services by the veterinary community, therefore, services and fees not previously included in the fee schedule have been added.

Federal Standard Statement

A Federal standards analysis is not required, since there are no applicable Federal standards that govern the operation of animal health fee for service diagnostic laboratories.

Jobs Impact

The proposed amendments will not result in the generation or loss of jobs in the State.

Agricultural Industry Impact

The proposed amendments will have a positive impact on New Jersey livestock owners by allowing the continued operation of the Department of Agriculture animal health diagnostic laboratory for the purposes of elective and voluntary disease control program diagnostics. Without continued implementation of this fee for service rule, the Department would not have the needed funding to continue to provide these services to livestock owners and veterinarians in the State. Even with the fee increases proposed by the Department, the livestock industry is assured of continued diagnostic services at or below the fees charged by comparable diagnostic laboratories.

Regulatory Flexibility Analysis

To the extent livestock owners are small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq., the proposed amendments impose compliance costs upon those livestock owners who choose to avail themselves of the services of the Department's animal health diagnostic laboratories. Livestock owners are required to pay fees for the services in accordance with the proposed fee schedule. Livestock owners continue to have the option to utilize the services of private laboratories.

The fees proposed to be imposed are necessary for the Department to recover its expenses and to continue to operate its animal health diagnostic laboratories within the confines of its existing budget. The Department has made no provision for small businesses in setting these fees because it has no funding with which to underwrite the cost of providing these laboratory services to small businesses at reduced or no charge.

No other reporting, recordkeeping or compliance requirements are imposed on small businesses under the proposed amendments. To the extent small businesses choose to use laboratory services providers other than the Department's animal health diagnostic laboratories, those livestock owners will incur the professional service fees of those laboratories. No other professionals are required to be retained to comply with the proposed amendments. No capital expenditures are required for compliance.

Smart Growth Impact

The proposed amendments will have no impact on smart growth or the State Development and Redevelopment Plan.

Housing Affordability Impact

The Department has found that there is an extreme unlikelihood that the scope the proposed amendments would change the average costs associated with housing. The rules pertain to animal diagnostic laboratory fees. Cost of housing is not affected.

Smart Growth Development Impact

The proposed amendments will have an insignificant impact on smart growth and there is an extreme unlikelihood that the regulation would evoke a change in housing production in Planning Areas 1 or 2 or within designated centers under the State Development and Redevelopment Plan in New Jersey because the rules pertain to animal diagnostic

laboratory fees.

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. FEE SCHEDULE

2:10-1.2 Fees

(a) For all veterinary diagnostic services for which there is no flat rate user fee listed--for instance, due to the introduction of a new test format--the hourly rate user fee will be calculated for the actual time, labor, administrative and material costs required to provide the service.

[page=6259] (b) Fees for bacteriology isolation and identification tests are as follows:

Technique -----	Charge -----
...	
Anaerobic isolation	\$ [23.00] 25.00
Salmonella.	\$ [18.00] 39.00
Mycologic and yeast	\$ [13.00] 18.00
Listeria.	\$ [20.00] 30.00
...	
Johne's culturing per animal.	\$ [19.50] 20.00
Leptospira microagglutination titer (MAT)	\$ 15.00

(c) Fees for virology identification tests are as follows:

Technique -----	Charge -----
HI serum titer.	\$ [15.00] 25.00

HI serum screen	\$ [7.80] 15.00
Serum neutralization.	\$ [13.00] 15.00
Direct fluorescent antibody (for agent)	\$ [9.25] 15.00
Indirect fluorescent antibody (for antibody).	\$ [14.50] 15.00
[IFA for PHF.	\$ 5.00
IFA for porcine reproductive respiratory syndrome	\$ 5.00
ELISA (horse)	\$ 11.00
ELISA (dog)	\$ 12.00]
IgM antibody capture ELISA.	\$ [19.00] 20.00
IgG antibody capture ELISA.	\$ [13.50] 20.00
...	

(d) Fees for serology are as follows:

Technique -----	Charge -----
[AGID Bovine Leucosis, part of a herd plan.	\$ 4.00 first animal; \$ 1.00 each additional animal
Bovine leucosis individual animal	\$ 6.00]
...	
[AGID Johne's	\$ 13.00]

...

[ELISA EIA. \$ 6.00]

ELISA \$ 20.00

...

(e) Fees for pathology are as follows:

Technique -----	Charge -----
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[Necropsy only. \$ 41.00

Necropsy histopathology only. \$ 61.00

Necropsy with infectious disease procedures \$ 162.00

Necropsy with all procedures. \$ 178.00]

**Necropsy small animal (up to 100 lbs), includes histology,
aerobic culture, and fecal \$ 70.00**

**Necropsy large animal (up to 300 lbs), includes histology,
aerobic culture, and fecal \$ 120.00**

**Necropsy poultry (up to five birds) includes histology,
aerobic culture, and fecal \$ 61.00**

...

[Histology per tissue (biopsies) \$ 25.00]

Histology (biopsies or "necropsy in bottle") up to three

tissues.	\$ 45.00
...	
Disposal fee (added to all necropsy procedures, except poultry)	\$ 25.00
Disposal fee (up to 150 lbs)	\$ 100.00

(f) Fees for test batteries or syndrome panels are as follows:

[Respiratory, equine (serum) -----	Charge -----
Equine herpes-1 SN.	\$ 15.00
Equine influenza HI	\$ 15.00
Equine viral arteritis SN	\$ 15.00
 Abortion, equine (serum) -----	
Equine herpes-1 SN.	\$ 15.00
Equine viral arteritis SN	\$ 15.00
Leptospira microagglutination titer MAT	\$ 15.00

Contagious equine metritis quarantine procedures

Quarantine supervision and laboratory testing: stallion.	\$ 1200.00
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Quarantine supervision and laboratory testing: mare.	\$ 500.00
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Respiratory, ruminant (serum)

Infectious bovine rhinotracheitis SN.	\$ 15.00
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Parainfluenza-3 HI.	\$ 15.00
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Bovine viral diarrhea SN.	\$ 15.00
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Abortion, ruminant (serum)

Bovine viral diarrhea SN.	\$ 15.00
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Infectious bovine rhinotracheitis SN.	\$ 15.00
---	----------

Leptospira MAT.	\$ 15.00
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Brucellosis (various official tests needed)	No Charge
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Fever of unknown origin with lameness and swelling (serum)

Equine viral arteritis HI	\$ 15.00
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Lyme disease ELISA.	\$ 15.00
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Lyme disease ELISA and western blot \$ 45.00
and EVA

Equine neurologic

Eastern equine encephalitis HI. \$ 15.00

Western equine encephalitis HI. \$ 15.00

West Nile virus disease HI. \$ 15.00

West Nile virus disease IgG \$ 15.00

West Nile virus disease IgM \$ 15.00

Equine herpes-1 SN. \$ 15.00]

Respiratory, equine \$ 40.00

Equine herpes-1 SN

Equine influenza HI

Equine viral arteritis SN

Abortion, equine (serum). \$ 40.00

Equine herpes-1 SN

Equine viral arteritis SN

Leptospira microagglutination titer MAT

Equine neurologic \$ 60.00

Eastern equine encephalitis HI

Western equine encephalitis HI

West Nile virus disease HI

West Nile virus disease IgG

West Nile virus disease IgM

Equine herpes-1 SN

Respiratory, ruminant (serum) \$ 40.00

Infectious bovine rhinotracheitis SN

Parainfluenza-3 HI

Bovine viral diarrhea SN

Abortion, ruminant (serum). \$ 40.00

Bovine viral diarrhea SN

Infectious bovine rhinotracheitis SN

Leptospira MAT

Brucellosis (various official tests needed) No charge

Equine Fever of unknown origin with lameness and

swelling (serum)..... **\$ 60.00**

Equine viral arteritis HI

Lyme disease ELISA

Lyme disease ELISA and western blot

Contagious equine metritis quarantine procedures

**Quarantine supervision and laboratory testing:
stallion..... **\$ 1,200.00****

**Quarantine supervision and laboratory testing:
mare..... **\$ 500.00****