

TITLE 3. FOOD AND AGRICULTURE

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (herein after referred to as "Department") is proposing to take the action described in the Informative Digest. A public hearing is not scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department no later than 15 days prior to the close of the written comment period. Any person interested may present statements or arguments in writing relevant to the action proposed to the person designated in this Notice as the contact person **beginning September 18, 2020 and ending on November 2, 2020**. Following the public hearing, if one is requested, or following the written comment period if no public hearing is requested, the Department, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 407, Food and Agricultural Code (FAC), and to implement, interpret, or make specific sections 24011, 24011.6, 24012, and 24015 of said Code, the Department is proposing to make changes to sections 1280.1, 1280.2, 1280.3, 1280.8, and 1280.11 of Chapter 6, Division 2, of Title 3 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Existing law, Chapter 8 (commencing with section 24000) of Division 11 of the FAC authorizes the Department to ensure the integrity of public horse shows, horse competitions, and horse sales through the control of performance and disposition enhancing medications while limiting their permitted therapeutic usage. The Department's Animal Health Branch, Equine Medication Monitoring Program (EMMP) enforces the requirements of these sections of law.

Existing section 24011 of the FAC makes it illegal to show, compete, or offer for sale a horse that has received a prohibited substance unless specified requirements have been met and facts requested are submitted to the Department, as specified.

Existing section 24011.6 of the FAC authorizes the therapeutic administration of a permissible substance before and during all events except public auctions, provided the dosage does not exceed limits or result in levels exceeding maximum permissible detectable levels as established by regulation.

Existing section 24012 of the FAC requires an event manager to charge, collect, and remit fees to the Department for events registered with the Department and establishes the authority to set the applicable fees by regulation.

Existing section 24015 of the FAC requires every equine event, as defined, to be registered with the Department and requires event managers to register events, as specified, and establishes penalties for failing to register.

Existing section 1280.1 of Title 3 of CCR requires event and public horse sale managers, as defined, to register equine events and sales, and to assess and remit fees collected to the Department, as specified, on forms incorporated by reference in the regulation text. The section also requires event exhibitors or consignors to complete and file with the event manager, a drug declaration form or compatible document, when any horse has received a prohibited substance for therapeutic reasons, as specified.

Existing section 1280.2 establishes fee amounts event managers assess, collect, and remit to the Department.

Existing section 1280.8 refers to the required use of the drug declaration form when a licensed veterinarian authorizes the administration of a therapeutic drug or medicine, as specified.

Existing section 1280.11 establishes fines and penalties for violations of the chapter.

This proposal amends section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are Americans with Disabilities Act (ADA) compliant.

The Department has evaluated this proposal and believes that it is not inconsistent or incompatible with existing State regulations. The Department is the sole State authority

over specified public equine events and sales pursuant to Chapter 8 (commencing with section 24000) of Division 11 of the FAC.

Anticipated Benefits of the Proposal: This proposal benefits the equine industry by promoting the safety of the horse and rider in competition and horses at public sales by preventing any potential misuse of drugs or medications that could fraudulently mask a disease, condition, or injury of the horse which could place the rider and/or the horse in jeopardy. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

Consistency and Compatibility with Existing State Regulations: The Department has evaluated this proposal and believes that it is not inconsistent or incompatible with the Department's existing State regulations regarding public equine events and sales. There are other State regulations dealing with the proper use of drugs and medications in equines under the California Horse Racing Board (Board) [Division 4 (commencing with section 1400) of Title 4 of the CCR] which is separate and distinct from the Department's EMMP. The Department has no jurisdiction over horse racing in the State yet work together with veterinarians of the Board to ensure a consistency of the programs within the State.

Documents Incorporated by Reference: None.

Technical, Theoretical, and Empirical Study, Report, or Similar Documents: No technical, theoretical, and empirical study, report, or similar documents were used in formulating this proposal.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code section 17500 et seq. Require Reimbursement: None.

Business Impact: The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

The Department has made an initial determination that the proposed regulatory action will not have any significant statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states.

The Department has made an initial determination that this regulatory proposal will impact the equine industry in California which may consist of persons and businesses required to register with the Department for any public horse events and sales held in California and affect persons and businesses choosing to participate in public horse events and sales in accordance with FAC section 24001, 24012, and 24015. The Department's proposal affects small businesses.

This proposal affects individuals and businesses choosing to participate in equine events and public sales throughout the State.

Cost Impacts on Representative Private Persons or Businesses: The Department is not aware of any cost impacts that representative private persons or businesses would necessarily incur in reasonable compliance with the proposed action. The proposed regulations affect individuals and businesses choosing to participate in various equine events held throughout California.

The anticipated compliance requirements as a result of this proposal:

Paperwork/reporting requirement: There are no new reporting requirements as a result of this proposal. This proposal amends section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant.

Effect on Housing Costs: None.

Effect on Small Business: The Department's proposal may affect small equine businesses choosing to participate in equine events and public sales throughout California.

RESULTS OF ECONOMIC IMPACT ASSESSMENT

Impact on Jobs/New Businesses: The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

Persons/Businesses affected by this proposal:

- Persons required to register for equine events - California hosts approximately 1,300 registered equine events annually, ranging from small backyard schooling (practice) shows to internationally recognized endurance events, as well as other types of competitions and public horse sales. This proposal will impact persons and businesses required to register with the Department for any public horse events and sales held in California in accordance with FAC sections 24001, 24012, and 24015.
- Persons choosing to participate in equine events - Equine events registered with the Department represent approximately 100,000 horse entries into competitions annually. For any equine that has received a permissible or prohibited substance, the owner/trainer/exhibitor must complete and file with an event manager an Official Form for Declaration of Drugs Administered, Form 76-027, as specified. On average, the Department receives 350-400 completed drug declaration forms per year. This proposal will impact persons and businesses choosing to participate in public horse shows and sales in accordance with FAC sections 24001, 24012, and 24015.

Benefits of the regulation to the health and welfare of California residents, worker safety, and the State's environment:

The Department is not aware of any specific benefits this proposal will have on the health of California residents, worker safety, or the State's environment.

The Department believes this proposal benefits the welfare of California residents by protecting the economic health of the affected equine industry. This proposal amends

section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant.

The above determinations are based on the fact that the proposed regulations assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

Occupations/Businesses Impacted: This proposal will impact the equine industry in California; will impact persons required to register with the Department for any public horse events and sales held in California, and affect persons choosing to participate in public horse events and sales in accordance with FAC sections 24001, 24012, and 24015. The Department's proposal affects small businesses.

Business Reporting Requirement:

Paperwork/reporting requirement: There are no new reporting requirements as a result of this proposal. This proposal amends section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant.

Comparable Federal Regulations: This proposal does not duplicate or conflict with federal regulations because there are no federal regulations governing public equine events or sales. The Department is the sole State authority over specified public equine events and sales pursuant to Chapter 8 (commencing with section 24000) of Division 11 of the FAC.

CONSIDERATION OF ALTERNATIVES

The Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the hearing (if a hearing is requested) or during the written public comment period.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Department has prepared an Initial Statement of Reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the Initial Statement of Reasons, and all the information upon which the proposal is based, may be obtained by contacting the persons named below or by accessing the Department's website as indicated below in this Notice.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the persons named below.

Any person may obtain a copy of the Final Statement of Reasons once it has been prepared, by making a written request to the contact persons named below or by accessing the website listed below.

CONTACT PERSONS

Inquiries and any written comments concerning this proposal are to be addressed to the following:

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Website Access: Materials regarding this proposal can be found by accessing the following Internet address: <http://www.cdfa.ca.gov/ahfss/regulations.html>

**DEPARTMENT OF FOOD AND AGRICULTURE
Animal Health Branch
PROPOSED REGULATION TEXT**

The Department of Food and Agriculture, Animal Health Branch, Equine Medication Monitoring Program, proposes the following changes to Chapter 6, (Drugging of Horses), Division 2 (Animal Industry) of Title 3 of the California Code of Regulations:

Amend the section heading and section 1280.1. of Chapter 6, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Section 1280.1. Event Registration.

~~(a) Every public equine event or public horse sale shall be registered with the Department pursuant to sections 24001, 24012 and 24015 of the Food and Agricultural Code.~~

~~(b)~~(a) The event manager is the "person in charge of an event", including the person responsible for registering the event with the Department and the person responsible for the assessment, collection, and remittance fees, and is personally liable for fees and penalties, if any, owed to the Department.

~~(c) The following forms, which are incorporated by reference, are required to be completed and sent to the Department according to the instructions contained on the forms:~~

~~(1) Application to Register Equine Event/Assessment Report For Registered Event, Form 76-024A (Rev. 08/19), is required at least 60 days in advance of the event. A fee of \$8.00 per horse entered per public show or sale must be assessed in accordance with section 1280.2 of these regulations. The assessment report must be submitted to the Department and fees remitted within fifteen (15) days after the final day of the event. Event managers are responsible for notifying the Department of Food and Agriculture of event changes or cancellations.~~

~~(2) Saleyard Assessment Report/Law Prohibiting Drugging of Horses, Form 76-025 (Rev. 08/19), must be filed by the sale manager within fifteen (15) days of the end of the month being reported. The assessment fee is \$8.00 for each horse consigned for public sale pursuant to section 1280.2 of these regulations.~~

~~(3) Official Form For Declaration Of Drugs Administered, Form 76-027 (Rev. 11/13) or a compatible document of the event sanctioning organization, must be completed by a registered event exhibitor or consignor and filed with the event manager for any horse that has received a prohibited substance for therapeutic reasons within three (3) days before a show/competition or five (5) days before a sale.~~

~~(A) The owner/exhibitor/trainer is to submit the completed Form 76-027 (Rev. 11/13) or a compatible document of the event sanctioning organization to the event~~

~~manager within one (1) hour if administration of the product(s) occurs at the event. If the product administration occurs at a time other than during show or sale hours, the owner or trainer should submit the completed form within one (1) hour after an event manager returns to duty.~~

(b) Every public equine event or public horse sale shall be registered with the Department pursuant to sections 24001, 24012, and 24015 of the Food and Agricultural Code, at least 60 days in advance of the event on the Application to Register Equine Event/Assessment Report for Registered Event, Form 76-024A as provided by the Department, or on-line at <http://apps4.cdfa.ca.gov/emppublic/eventregistration.aspx>. To register events using Form 76-024A, sections (1) and (2) must be completed and the application form returned to the Department at least 60 days prior to the event start date. The Department, upon receipt of Form 76-024A, shall issue an event number, document the event number on the form, and return the form to the event manager to be used for the remittance of fees collected pursuant to subsection (c) below for public equine events. Form 76-024A shall include:

(1) Event information including: name of event; event start date, event end date, and start time; number of equines expected; facility name and facility address (or geographic location) including city, zip code, and county; event type (English, Western, etc.); and sponsor organization, if applicable.

(2) Event manager information including: last name and first name; mailing address including city, state, and zip code; primary telephone number; alternate telephone number or fax; e-mail address, and event alternate contact information including last name and first name, telephone number, and e-mail address.

(3) Payment information including: number of horses assessed; fees collected (number of horses entered in the registered event multiplied by the applicable fee in accordance with section 1280.2); pursuant to Food and Agricultural Code section 24012, a 10% penalty shall be applied when fees are not submitted within 15 days of the event end date and an additional 1.5% interest penalty shall be applied when fees are not submitted within 30 days; total amount due to the Department; and check number when fees are remitted by check.

(4) Signature of event manager and date signed (and date the event was cancelled, if applicable).

(c) Event managers are responsible for notifying the Department of event changes or cancellations.

Note: Authority cited: Sections 407 and 24013, Food and Agricultural Code. Reference: Sections 24001, 24012 and 24015, Food and Agricultural Code.

Amend section 1280.2. of Chapter 6, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Section 1280.2. Fees.

(a) The event manager is responsible for the assessment, collection, and remittance of fees, and is personally liable for fees and penalties, if any, owed to the Department.

(b) Beginning January 1, 2020, the applicable fee is \$8.00 per horse entered per event, except where a horse is entered in simultaneous multiple events held as single performances, the total applicable fee per horse shall be \$8.00.

(c) Event managers of public equine events must assess, collect, and remit fees to the Department within 15 days of the event end date using the Application to Register Equine Event/Assessment Report for Registered Event, Form 76-024A as provided by the Department, or on-line at <https://secure.cdfa.ca.gov/egov/emmp/>. To remit fees using Form 76-024A, sections (3) and (4) of the form as described in section 1280.1(b)(3) and (4) must be completed and the form with fees collected in the amount due, returned to the Department within 15 days after the final day of the event.

(d) Saleyard managers of public horse sales must assess and collect fees for all public horse sales held during a one-month period, and remit fees to the Department within 15 days of the end of the month being reported either on-line at <https://secure.cdfa.ca.gov/egov/emmp/> or by using the Saleyard Assessment Report, Form 76-025 as provided by the Department and the form shall include:

- (1) Name of sale;
- (2) Date of sale;
- (3) Facility name and address (or geographic location) where the event will be held;
- (4) Facility mailing address;
- (5) Telephone number of saleyard;
- (6) First and last name of saleyard manager;
- (7) First and last name of an alternate contact;
- (8) Payment information including: number of horses assessed; fees collected (number of horses consigned for public sale multiplied by the applicable fee in accordance with section 1280.2); pursuant to Food and Agricultural Code section 24012, a 10% penalty shall be applied when fees are not submitted within 15 days of the end of the month reported and an additional 1.5% interest penalty shall be applied when fees are not submitted within 30 days of the end of the month reported; total amount due to the Department; and check number when fees are remitted by check.
- (9) Signature of the saleyard manager and date signed.

Note: Authority cited: Sections 407, 24012 and 24013, Food and Agricultural Code.
Reference: Section 24012, Food and Agricultural Code.

Amend the section heading and section 1280.3 of Chapter 6, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Section 1280.3. ~~Testing of Horses~~ Declaration of Drugs Administered.

(a) Show or competition horses receiving a prohibited substance for therapeutic reasons are not be eligible for show or competition for a period of not less than 24 hours after receiving the prohibited substance.

(b) Sale horses receiving a permissible substance or prohibited substance for therapeutic reasons are not eligible for a public sale for a period of not less than 72 hours after receiving the permissible or prohibited substance.

(c) Any horse receiving anabolic steroids for therapeutic reasons shall be withdrawn from show, competition, or sale for 90 days after the administration of the anabolic steroid and for 45 days after the administration of fluphenazine or reserpine.

(d) Registered event exhibitors/owners/trainers must make a declaration of drugs administered pursuant to Food and Agricultural Code section 24011 and as specified in subsection (f) below for any horse that has received a prohibited substance for therapeutic reasons within three (3) days before a show/competition.

(e) Registered sale consignors must make a declaration of drugs administered in accordance with subsection (f) below for any horse that has received a permissible substance or a prohibited substance for therapeutic reasons within five (5) days before a sale.

(f) All declarations of drugs administered must be filed with the event manager on a completed Declaration of Drugs Administered, Form 76-027 as provided by the Department within one (1) hour of administering the product(s) if the administration occurs at the event or within one (1) hour after an event manager returns to duty if the administration occurs at a time other than during event hours. The Declaration of Drugs Administered form shall include:

- (1) Name and date of event;
- (2) Time and date of declaration;
- (3) Horse entry number;
- (4) Name, age, sex, color, and breed of horse;
- (5) Product name of drug or medication administered;
- (6) Amount, mode/route of administration (oral/injection/topical), and size/concentration/strength of drug or medication administered;
- (7) Diagnosis and reason for administering the medication;
- (8) Time and date of administration;

- (9) Name and signature of person administering the drug or medication;
- (10) Name, address, and telephone number of horse's owner; and
- (11) Name and signature of the event manager receiving the declaration, which acknowledges the form is complete, including the date and time received.

(g) Event managers of public equine events shall submit all Declaration of Drugs Administered, Form 76-027 received pursuant to this section to the Department within 15 days of the completion of the event, and for saleyard managers of public horse sales within 15 days of the end of the month reported.

(h) Information provided on the Declaration of Drugs Administered, Form 76-027 in conjunction with any other relevant evidence shall be considered by the Department in determining whether a violation has occurred.

Note: Authority cited: Sections 407, ~~24007 and 24008~~ 24011, and 24013 Food and Agricultural Code. Reference: Sections ~~24000-24018~~ 24003, 24004, and 24006, Food and Agricultural Code.

Amend section 1280.8. of Chapter 6, Division 2, of Title 3 of the California Code of Regulations, to read as follows:

Section 1280.8. Therapeutic Drugs and Medicines.

(a) Therapeutic drugs or medicines administered for purposes other than under veterinary prescription for a diagnosed illness or injury are considered prohibited substances, and their use is a violation of this section.

(b) Horses administered therapeutic drugs or medicines for purposes other than under veterinary prescription for a diagnosed illness or injury shall not compete or be available for sale until the prohibited substance is no longer detectable in the urine or blood sample.

(c) A therapeutic drug or medicine is permitted when:

(1) A prohibited substance is administered more than 24 hours before competition or more than 72 hours before a public sale.

(2) The therapeutic drug or medicine, or metabolite of the therapeutic drug or medicine, does not interfere with the quantification of any permitted substance or detection of any prohibited substances as defined by Food and Agricultural Code section 24001(h).

(3) Only one (1) nonsteroidal anti-inflammatory drug (NSAID) is given. When two NSAIDs are in a therapeutic regime, one must be discontinued at least 72 hours before competition.

(A) When administered by a licensed veterinarian for the emergency treatment of colic or an ophthalmic emergency, flunixin, in addition to one (1) other NSAID, may be acceptable if found in the plasma or urine sample of a horse provided:

(i) The licensed veterinarian who administered the substances properly signs and files a drug ~~d~~Declaration of Drugs Administered, [Form 76-027(Rev. 11/13)] with the event manager or designee within one (1) hour after administration of the substances or one (1) hour after the event manager or designee returns to duty if the administration occurs at a time outside competition hours; and

(ii) The horse is withdrawn from competition for 24 hours or from public sale for 72 hours.

(4) The detected level in the sample does not exceed the established maximum detectable plasma levels for the following drug or medicine:

- (A) 15.0 micrograms per milliliter of phenylbutazone.
- (B) 1.0 micrograms per milliliter of flunixin.
- (C) 2.5 micrograms per milliliter of meclofenamic acid.
- (D) 40 micrograms per milliliter of naproxen.
- (E) 0.240 micrograms per milliliter of firocoxib.
- (F) 0.005 micrograms per milliliter of diclofenac.
- (G) 0.250 micrograms per milliliter of ketoprofen.
- (H) 0.0005 micrograms per milliliter of dexamethasone.
- (I) 0.5 micrograms per milliliter of methocarbamol.

(5) The detected level in the sample does not exceed the established maximum detectable urine levels for the following drug or medicine:

- (A) 0.09 micrograms per milliliter of dexamethasone.
- (B) 350 micrograms per milliliter of methocarbamol.

(d) No injectable substance shall be given to a horse within 12 hours of competition except:

(1) A minimum of 1 liter of polyionic fluids per 100 pounds of body weight given therapeutically by a licensed veterinarian between 6-12 hours of competition.

Therapeutic fluids with concentrated electrolytes, such as magnesium, are prohibited.

(2) Antibiotics, except procaine penicillin G, administered by a licensed veterinarian between 6-12 hours of competition.

(3) Dexamethasone, not to exceed 0.5 milligram per 100 pounds, administered by a licensed veterinarian between 6-12 hours of competition exclusively for the treatment of acute urticaria (hives). The total dose of dexamethasone administered within 24 hours shall not exceed 1.0 mg per 100lbs.

(4) The licensed veterinarian who administered the injectable substances in (d)(1) through (3) above shall sign and file a drug ~~d~~Declaration of Drugs Administered, [Form 76-027(Rev. 11/13)] with the event manager or designee within one (1) hour after the administration of the injectable substance or one (1) hour after the event manager or designee returns to duty if the administration occurs at a time outside competition hours.

Note: Authority cited: Sections 407, 24011.6 and 24013, Food and Agricultural Code.
Reference: Sections 24003, 24004, 24006, 24008, 24009 and 24011, Food and
Agricultural Code.

**Amend section 1280.11. of Chapter 6, Division 2, of Title 3 of the California Code
of Regulations, to read as follows:**

Section 1280.11. Fines and Penalties.

(a) Failure to comply with the provisions of this Chapter or Chapter 8 (commencing with section 24000) of Division 11 of the Food and Agricultural Code, and any regulations adopted pursuant to them, constitutes a violation punishable by a fine of not less than one hundred dollars (\$100) or more than ten thousand dollars (\$10,000). The Department shall use the provisions of this section to determine the violation class and amount of the penalty.

(b) For the purposes of this section, violation classes are designated as “serious,” “moderate,” and “minor” to establish maximum penalty amounts. Repeat violations may result in an escalation of violation class. Serious and moderate violations may be downgraded based upon the evidence, the factual circumstances, mitigating factors and the cooperation of the violator.

(1) “Serious.” Violations that cause significant performance enhancement of the equine or deceptive business practices that include the second offense, third offense, and any subsequent offenses for failure to submit a horse for sample collection; the first offense, second offense, and any subsequent offenses for detection of a non-therapeutic prohibited substance; the second offense and any subsequent offenses for detection of therapeutic prohibited substances; the third offense and any subsequent offenses for detection of two Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in a sample; the third offense and any subsequent offenses for detection of a permissible substance over the maximum detectable plasma level; and the second offense, third offense, and any subsequent offenses for administration of a prohibited injectable substance within 12 hours of competition. Serious violations also include the third offense and any subsequent offenses for failure of an event manager to register an event at least 60 days in advance of the event and the third offense and any subsequent offenses for failure of an event manager to submit fees within 15 days after the final day of the event.

(A) The suspended individual is not permitted entry to the grounds of any registered event in the state of California during the suspension period. Event managers may not permit participation of a suspended individual in the registered event and event managers must immediately notify the Department of a suspended individual's presence on the event grounds. Event managers who permit participation of a suspended

individual are subject to a violation and civil penalty in accordance with Food and Agricultural Code sections 24007 and 24015(c).

(2) "Moderate." Violations in which there is a potential for intermediate level of competitive harm that include the first offense for failure to submit a horse for sample collection; the first offense for detection of a therapeutic prohibited substance; the second offense for detection of a permissible substance over the maximum detectable plasma level; the second offense for detection of two Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in a sample; and the first offense for administration of a prohibited injectable substance within 12 hours of competition. Moderate violations also include the second offense for failure of an event manager to register an event at least 60 days in advance of the event and the second offense for failure of an event manager to submit fees within 15 days after the final day of the event.

(3) "Minor." Violations that are unintentional and have minimal performance enhancing action in the competition, including the first offense for detection of a permissible substance over the maximum detectable plasma level and the first offense for detection of two Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in a sample. Minor violations also include the first offense for failure of an event manager to register an event at least 60 days in advance of the event and the first offense for failure of an event manager to submit fees within 15 days after the final day of the event. The Department may issue a notice of warning for minor violations.

(c) Table "A" Equine Medication Monitoring Program Violations Matrix is to be used to establish the level of severity of a particular violation and the corresponding penalty range for "serious," "moderate," and "minor" violation classes.

TABLE A: EQUINE MEDICATION MONITORING PROGRAM VIOLATIONS MATRIX

| Title 3, CCR Section | Description of the Violation | Minor | Moderate | Serious | Penalty |
|---|--|-------|----------|---------|---|
| <u>1280.1(e)(1)</u> <u>1280.1(b)</u> | Failure of Event Manager to Register Event at least 60 days in advance of the event – First Offense | X | | | Violations may be assessed at a minimum of \$100 up to \$500. |
| <u>1280.1(e)(1)</u> <u>1280.1(b)</u> | Failure of Event Manager to Register Event at least 60 days in advance of the event – Second Offense | | X | | Violations may be assessed at a minimum of \$500 up to \$2,000. |
| <u>1280.1(e)(1)</u> <u>1280.1(b)</u> | Failure of Event Manager to Register | | | X | Violations may be assessed at a |

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| | Event at least 60 days in advance of the event – Third Offense and any subsequent offenses | | | | minimum of \$2,000 up to \$10,000. |
| <u>1280.1(e)(1)</u> <u>1280.2(c)</u> | Failure of Event Manager to Submit Fees within 15 days after the final day of the event – First Offense | X | | | Violations may be assessed at a minimum of \$100 up to \$500 plus civil penalties of 10% of the amount due plus interest rate of 1.5% per month. |
| <u>1280.1(e)(1)</u> <u>1280.2(c)</u> | Failure of Event Manager to Submit Fees within 15 days after the final day of the event – Second Offense | | X | | Violations may be assessed at a minimum of \$500 up to \$2,000 plus civil penalties of 10% of the amount due plus interest rate of 1.5% per month. |
| <u>1280.1(e)(1)</u> <u>1280.2(c)</u> | Failure of Event Manager to Submit Fees within 15 days after the final day of the event – Third Offense and any subsequent offenses | | | X | Violations may be assessed at a minimum of \$2,000 up to \$10,000 plus civil penalties of 10% of the amount due plus interest rate of 1.5% per month. |
| 1280.7(b) | Failure to Submit Horse for Sample Collection – First Offense | | X | | Violations may be assessed at a minimum of <u>\$1,000</u> to <u>\$2,000</u> . |
| 1280.7(b) | Failure to Submit Horse for Sample Collection – Second Offense | | | X | Violations may be assessed at a minimum of \$5,000 to \$10,000. |

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|--------------|--|--|---|---|---|
| 1280.7(b) | Failure to Submit Horse for Sample Collection – Third Offense and any subsequent offenses | | | X | Violations may be assessed at \$10,000 and possible suspension of the owner, trainer or both from competition for 90 days to one year. |
| 1280.8(b) | Detection of a Non-Therapeutic Prohibited Substance – First Offense | | | X | Violations may be assessed at a minimum of \$2,000 up to \$5,000 and possible suspension of the owner, trainer or both from competition for 90 days to one year. |
| 1280.8(b) | Detection of a Non-Therapeutic Prohibited Substance – Second Offense and any subsequent offenses | | | X | Violations may be assessed at a minimum of \$5,000 up to \$10,000 and possible suspension of the owner, trainer or both from competition for 90 days to one year. |
| 1280.8(c)(1) | Detection of a Therapeutic Prohibited Substance – First Offense | | X | | Violations may be assessed at a minimum of \$1,000 up to \$2,000. |
| 1280.8(c)(1) | Detection of a Therapeutic Prohibited Substance – Second Offense and any subsequent offenses | | | X | Violations may be assessed at a minimum of \$2,000 up to \$10,000 and possible suspension of |

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|--------------|---|---|---|---|--|
| | | | | | the owner, trainer or both from competition for 90 days to one year. |
| 1280.8(c)(3) | Detection of two Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in a sample – First Offense | X | | | Violations may be assessed at \$500. |
| 1280.8(c)(3) | Detection of two Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in a sample – Second Offense | | X | | Violations may be assessed at a minimum of \$1,000 up to \$2,000. |
| 1280.8(c)(3) | Detection of two Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in a sample – Third Offense and any subsequent offenses | | | X | Violations may be assessed at a minimum of \$2,000 up to \$10,000. |
| 1280.8(c)(4) | Detection of a permissible substance over the maximum detectable plasma level – First Offense | X | | | Violations may be assessed at \$500. |
| 1280.8(c)(4) | Detection of a permissible substance over the maximum detectable plasma level – Second Offense | | X | | Violations may be assessed at a minimum of \$1,000 up to \$2,000. |
| 1280.8(c)(4) | Detection of a permissible substance over the maximum detectable plasma level – Third Offense and any subsequent offenses | | | X | Violations may be assessed at a minimum of \$2,000 up to \$10,000. |
| 1280.8(d) | Administration of a prohibited injectable substance within 12 hours of competition – First Offense | | X | | Violations may be assessed at a minimum of \$1,000 up to \$2,000. |

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|-----------|--|--|--|---|--|
| 1280.8(d) | Administration of a prohibited injectable substance within 12 hours of competition – Second Offense | | | X | Violations may be assessed at a minimum of \$2,000 up to \$5,000. |
| 1280.8(d) | Administration of a prohibited injectable substance within 12 hours of competition – Third Offense and any subsequent offenses | | | X | Violations may be assessed at a minimum of \$5,000 up to \$10,000 and possible suspension of the owner, trainer or both from competition for 90 days to <u>one</u> year. |

Note: Authority cited: Sections 407 and 24013, Food and Agricultural Code. Reference: Sections 24002, 24003, 24004, 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24011.6, 24012 and 24015, Food and Agricultural Code.

**DEPARTMENT OF FOOD AND AGRICULTURE
Animal Health Branch
INITIAL STATEMENT OF REASONS**

Subject Matter of Proposed Regulation

Equine Medication Monitoring Program - Forms

Sections Affected

Sections 1280.1, 1280.2, 1280.3, 1280.8, and 1280.11

Specific Purpose of Each Adoption, Amendment, or Repeal

Existing law, section 407 of the Food and Agricultural Code (FAC), provides that the Secretary may adopt such regulations as are reasonably necessary to carry out the provisions of the code which she is directed or authorized to administer or enforce.

Existing law, Chapter 8 (commencing with section 24000) of Division 11 of the FAC authorizes the Department of Food and Agriculture (Department) to ensure the integrity of public horse shows, horse competitions, and horse sales through the control of performance and disposition enhancing medications while limiting their permitted therapeutic usage. The Department's Animal Health Branch, Equine Medication Monitoring Program (EMMP) enforces the requirements of these sections of law. More specifically, FAC:

- Section 24011 makes it illegal to show, compete, or offer for sale a horse that has received a prohibited substance unless specified requirements have been met and facts requested are submitted to the Department, as specified.
- Section 24011.6 authorizes the therapeutic administration of a permissible substance before and during all events except public auctions, provided the dosage does not exceed limits or result in levels exceeding maximum permissible detectable levels as established by regulation.
- Section 24012 requires an event manager to charge, collect, and remit fees to the Department for events registered with the Department, and establishes the authority to set the applicable fees by regulation.

- Section 24015 requires every equine event, as defined, to be registered with the Department and requires event managers to register events, as specified, and establishes penalties for failing to register.

Existing section 1280.1 of Title 3 of the California Code of Regulations (CCR) requires event and public horse sale managers, as defined, to register equine events and sales, and to assess and remit fees collected to the Department, as specified, on forms incorporated by reference in the regulation text. The section also requires event exhibitors or consignors to complete and file with the event manager, a drug declaration form or compatible document, when any horse has received a prohibited substance for therapeutic reasons, as specified.

Existing section 1280.2 establishes fee amounts event managers assess, collect, and remit to the Department.

Existing section 1280.8 refers to the required use of the drug declaration form when a licensed veterinarian authorizes the administration of a therapeutic drug or medicine, as specified.

Existing section 1280.11 establishes fines and penalties for violations of the chapter.

This proposal amends section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are Americans with Disabilities Act (ADA) compliant.

The Department is proposing to use the form exemption in Government Code section 11340.9(c) which provides that a form prescribed by a state agency or any instructions relating to the use of the form is exempt from the Administrative Procedure Act (APA) if it only contains matter that has been, or does not need to be, adopted pursuant to the APA which is accomplished by listing all the substantive requirements for each form in the regulation text as is proposed in this rulemaking.

Problem(s) Intended to Address

Equine Medication Monitoring Program forms used for the registration, assessment, and remittance of fees for equine events and sales, and for the reporting of equine medications used, are incorporated by reference, which does not allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant.

Statement of Factual Basis and Rationale

The Animal Health Branch is the State's professional veterinary medical unit that protects livestock, consumers, and California's economy from catastrophic animal diseases and other health issues. It addresses diseases and other issues that cannot be successfully controlled on an individual animal or herd basis but require statewide coordinated efforts. The Branch is responsible for deterring any activities that have the potential to compromise California's abundant food supply or the safety of public and animal health.

California is the only state with a state-based, industry-funded horse drug testing program that targets sample collections from horses entered in public equine events. The California equine industry sponsored legislation in 1971 to prohibit the misuse of drugs and medications in horses, ponies, mules, and donkeys in public shows, competitions and sales. The intent of the EMMP is to ensure the integrity of public horse shows, competitions, and sales through the control of performance and disposition-enhancing drugs, and to allow limited therapeutic use of drugs at an equine event. The EMMP monitors equines in public shows, competitions, and sales through random collection of blood or urine for chemical analysis. The California Equine Medication Rule prohibits use of certain drugs or drug combinations yet accommodates specific legitimate therapeutic use of medications within specified parameters.

California hosts approximately 1,300 registered equine events annually, ranging from small backyard schooling shows to internationally recognized endurance events, as well as other types of competition and public horse sales, totaling approximately 100,000 horses competing per year. Less than 25 percent of California's 1,300 events are registered with the national governing body, the United States Equestrian Federation, which enforces drugs and medication rules for nationally sanctioned events. Thus, most of the shows in the State are regulated by the Department's EMMP to ensure compliance with drugs and medication rules.

The EMMP is entirely industry funded. Event managers collect applicable fees from persons entering horses in shows and competitions or consigned to public sales. The event manager remits the fees to the Department and they are deposited into the

Department of Food and Agriculture Fund. The drug testing fees are exclusive of any other fees charged by the industry for the administration and management of equine events, such as entry fees, stall fees, grounds fees, and training fees.

Event managers, in addition to collecting and remitting fees as discussed above, are required to register (advise and record) the event with the EMMP at least 60 days in advance of the scheduled event. Event managers are required to register events using the Department provided Application to Register Equine Event/Assessment Report for Registered Events, Form 76-024A which is available by download from the Department's website, upon request by telephoning the Department, or upon request via Department e-mail. Event managers may also register events through an on-line registration process available by accessing the Department's webpage. Form 76-024A is additionally used to remit to the Department fees collected by event managers at registered competition events. Public horse sale managers use the Saleyard Assessment Report/Law Prohibiting Drugging of Horses, Form 76-025 to remit fees to the Department for public horse sale events. Event managers failing to comply with EMMP regulations are subject to civil penalties for each violation.

As registered equine events approach, EMMP field personnel receive assignments to randomly select equines competing in or consigned to a registered event for sample collection. Any equine on an event premises is subject to random selection for sampling and testing. Equine Medication and Monitoring Program field personnel are trained to collect urine samples, however when a California-licensed veterinarian is assigned to work with EMMP field staff, the selected equines are subject to collection of a blood sample.

For equine owners/trainers/exhibitors and consignors, an Official Form for Declaration of Drugs Administered, Form 76-027, which is available upon request from event managers, must be completed and filed with the event manager for any equine that has received a prohibited substance. Additionally, an owner/trainer/exhibitor must complete and file Form 76-027 for any equine that has received a prohibited substance within the three (3) days before the day being shown or for consignors, within the five (5) days before the day of the sale for any horse receiving a permissible or prohibited substance.

This proposal repeals the existing three (3) program forms used for registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form.

This proposal is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

The Department is now proposing to amend the regulations as follows:

Section 1280.1

The Department is amending the section heading of section 1280.1 to add "Event" which is necessary to clarify the topic of the section.

The Department is proposing to delete existing subsection (a) and relocate and amend the requirement in proposed subsection (b) as discussed below.

The Department is proposing to amend existing subsection (b) to read as proposed *subsection (a)*.

The Department is proposing to delete existing subsections (c), (c)(1), (c)(2), (c)(3), and (c)(3)(A) to remove forms incorporated by reference which is necessary to allow the EMMP to revise forms as necessary to keep program forms up to date and to ensure ADA compliance of program forms provided to the public for use. The Department is proposing to relocate the additional requirements stated in these subsections to various proposed subsections throughout this proposal.

Subsection (b) relocates deleted text in existing section 1280.1(a) requiring the registration of every public event or public horse sale pursuant to the FAC. The section also prescribes all equine events must be registered with the Department at least 60 days in advance of the event and specifies use of the Application to Register Equine Event/Assessment Report for Registered Events, Form 76-024A [deleted section 1280.1(c)(1)], as provided by the Department. These amendments are necessary to reference the authority for the requirement to register events and the manner in which to complete the registration within the same section. Event managers may obtain Form 76-024A by contacting the Department or by accessing the Department's webpage to print a copy of the form or may register the event electronically using the EMMP's on-line registration system as stated.

Registration of an event using Form 76-024A requires the collection of basic event and event manager contact information which is necessary because it is used by the EMMP to assign field personnel to equine events for testing and will later serve to link registered events to fee amounts collected and remitted to the Department by the event manager at the conclusion of events.

Subsection (b) requires event managers to complete sections (1) and (2) of Form 76-024A and to return the form to the Department at least 60 days prior to the event start date. The subsection continues to state that when the Department receives a completed event registration, the event is given a registration number which is generated by the Department and documented on the registration form. Equine Medication Monitoring Program staff retain a copy of the form for internal processing and cross-reference and return a copy to event managers of public equine events for remittance of fees pursuant to subsection (c). These amendments are necessary to inform the public how to complete the form and of the processes and procedures used by the EMMP to register equine events.

Subsections (b)(1) and (b)(2) specify information requested on the form when event managers register events and include: name of the event; event start and end dates, and start time; number of equines expected; event type (English, Western, etc.); facility name and address or location; event manager's name, mailing address, primary and alternate telephone numbers, fax number, and e-mail; an alternate contact name, telephone number, and e-mail; and signature of event manager and date signed. This information is necessary to identify the event, and the time and place it will take place to allow the EMMP to assign tester staff to specific events based on location in the State and to contact event managers when necessary.

Subsections (b)(3) and (4) specify information requested on the form when event managers of public equine events remit fees to the Department within 15 days of the last day of the event and include: number of horses assessed; fee amount collected (number of horses entered in the registered event multiplied by the applicable fee in accordance with section 1280.2; a 10% penalty must be applied if fees are not submitted within 15 days of the last day of the event and an additional 1.5% interest penalty must be applied when fees are not submitted within 30 days of the last day of the event pursuant to FAC section 24012; total amount due; and check number when fees are remitted by check or on-line payments can be made. A signature of the event manager with date is also required, and space is provided for the date an event is cancelled, if applicable. These amendments are necessary to document an accurate calculation of the number of horses and the applicable fees collected by the event manager when remitting fees owed to the Department.

Subsection (c) restates the language in deleted subsection 1280.1(c)(1) clarifying that event managers are responsible for notifying the Department when there are event changes or cancellations. This requirement is necessary because workload assignments for sample collection by EMMP field personnel at events are made based upon the date and location information provided when event managers register events. Notification of an event cancellation can be made to the EMMP via telephone, return of Form 76-024A with the "Date Cancelled" field completed, or by electronic means. Relocation of this requirement is necessary for clarity as this proposed location keeps all the requirements with respect to registering and cancelling events within the same section.

Section 1280.2

Subsection (a) is added and necessary to clarify the responsibility of the event manager with respect to assessing, collecting, and remitting fees to the Department pursuant to the section.

The Department is adding outline formatting to the existing regulation text to read as *subsection (b)*.

Subsection (c) prescribes the requirement for event managers to assess, collect, and remit fees to the Department within 15 days after the final day of the event using the Application to Register Equine Event/Assessment Report for Registered Events, Form 76-024A, or on-line payments can be made, authorized by FAC section 24012. This requirement in part, is relocated from deleted 1280.1(c)(1). Relocation of this requirement is necessary for clarity as this proposed location keeps all the requirements with respect to using the form for fee remittance within the same section.

Subsection (c) clarifies that section (3) and (4) of Form 76-024A as described in section 1280.1(b)(3) and (4) must be completed and the form with fees collected in the amount due, returned to the Department. The amendments in subsection (c) are necessary to inform the public of the processes and procedures required of event managers of public equine events when remitting fees to the Department.

Subsection (d) prescribes the requirement for saleyard managers of public horse sales to assess, collect, and remit fees to the Department within 15 days of the end of the month being reported using the Saleyard Assessment Report/Law Prohibiting Drugging of Horses, Form 76-025, or on-line payments can be made, authorized by FAC section 24012. This requirement is relocated in part, from deleted section 1280.1(c)(2). Relocation of this requirement is necessary for clarity as this proposed location keeps all the requirements with respect to fee remittance within the same section. Public horse

sales generally operate on a weekly basis, at the same location, and managed by the same sale owner/operator. Requiring public horse sale event managers to submit fees to the Department after every event (weekly) would be burdensome, therefore, the Department requires event managers of public horse sales to remit fees on a monthly basis and remit fees using a Form 76-025 as provided.

Subsections (d)(1) through (9) describe the contents of form 76-025 to include: name of the sale, facility name and address or location, facility mailing address; name of the event manager; telephone number of the saleyard; date of the sale; number of horses assessed; amount due; if applicable, a 10% penalty must be applied if fees are not submitted within 15 days of the last day of the end of the month being reported and an additional 1.5% interest penalty must be applied when fees are not submitted within 30 days of the end of the month being reported pursuant to FAC section 24012; and check number (or fees may be remitted on-line). A signature of the saleyard manager with date is also required. These amendments are necessary to document saleyard location and contact information, to calculate fees owed to the Department, and provides instruction to the saleyard manager for remittance of those fees.

Section 1280.3

The Department is amending the heading of section 1280.3 to read “Declaration of Drugs Administered” for clarity.

Add *subsections (a), (b), and (c)*. Although regulation is not supposed to be duplicative, the Department believes it is necessary to repeat portions of the FAC section 24011 in added subsections (a), (b), and (c) so the section is comprehensive and makes it easy for the public and industry to understand and follow the requirements and eliminates the need to read both the FAC and this regulation to comply with a declaration of drugs administered.

The Department is adding *subsection (d)* which replaces in part, the requirements deleted in section 1280.1(c)(3) specifying that registered event exhibitors/owners/trainers must make a declaration of drugs administered for any horse that has received a prohibited substance for therapeutic reasons within three (3) days before a show or competition. Relocation of this requirement is necessary for clarity as this proposed location keeps all the requirements with respect to declaring use of drugs by exhibitor/owners/trainers and using the form within the same section. The subsection states that event “exhibitors/owners/trainers” are responsible for this reporting as specified in the FAC which is necessary for clarity to identify those responsible for the declaration of drugs administered. Reporting the administration of prohibited substances given within three

(3) days before a show or competition is necessary because the substance(s) may still be detectable even though they were (lawfully) given to the animal outside of the restricted 24-hour period as specified in subsection (a). The subsection references subsection (f) for making a declaration of drugs administered using the Department provided form which is necessary to inform the public use of the form is a requirement.

The Department is adding *subsection (e)* which replaces in part, the requirements deleted in section 1280.1(c)(3) specifying registered sale consignors must make a declaration of drugs administered for any horse that has received a permissible substance or a prohibited substance for therapeutic reasons with five (5) days before a sale. Relocation of this requirement is necessary for clarity as this proposed location keeps all the requirements with respect to declaring use of drugs by sale consignors and using the form within the same section. The Department is adding “permissible substance” as it was inadvertently omitted in the existing regulation text and necessary to make this section consistent with the wording of FAC section 24011. Reporting the administration of permissible and prohibited substances given within five (5) days before a sale is necessary because the substances may still be detectable even though they were (lawfully) given to the animal outside of the restricted 72-hour period as specified in subsection (b). The subsection references subsection (f) for making a declaration of drugs administered using the Department provided form which is necessary to inform the public use of the form is a requirement.

Subsection (f) requires use of the Department’s Declaration of Drugs Administered, Form 76-027 by registered event exhibitors/owners/trainers and sale consignors when making a declaration of drugs administered [deleted subsection 1280.1(c)] as required by proposed subsections (d) and (e). The subsection states that the completed form must be provided to the event manager within one (1) hour of administration if the administration occurred at the event or within one (1) after the event manager returns to duty if the administration occurred at a time other than during the event hours. This requirement is necessary to inform exhibitors/owner/trainers and sale consignors that the form is to be submitted within a specific time period. In the past, declarations of drugs administered have been completed several hours or even days after the administration of a substance and because of this, the information was inaccurately recorded resulting in disputes between the chemical analysis of test specimens and information provided on the form. To resolve the recording of inaccurate information, the Department finds it necessary to require the reporting of drugs administered to the event manager within one (1) hour after the administration of the drug(s), as specified. This requirement is relocated from deleted section 1280.1(c)(3)(A) which is necessary for clarity as this proposed location keeps all the requirements with respect to declaring use of drugs within the same section.

Subsections (f)(1) through (11). The Official Form for Declaration of Drugs Administered, Form 76-027 requests the recording of specific information pertaining to the administration of the permissible or prohibited substances required by FAC section 24011 and is stated in subsections (f)(1) through (11) to include: name and date of event; time and date of drug declaration; horse entry number, name, age, sex, color, and breed; and product name of drug or medication administered, amount, mode/route of administration (oral/injection/topical), size/concentration/strength of drug or medication administered, diagnosis and reason for administering the medication, and time and date of administration. The form requires the name and signature of person administering the drug or medication; the name, address and telephone number of horse's owner; and the name and signature of the event manager receiving the declaration, which acknowledges the form is complete pursuant to FAC section 24011, and the date and time of receipt. The above information is necessary to link samples taken to declarations made and to provide information to contact the owner if necessary, when a violation occurs. If a sample is positive, the Department refers to the drug declaration to verify accuracy and compare the test results to the information provided with respect to the drug administered and the amount and concentration administered. In the event of a violation, this same information may be used to impose penalties and fines or suspensions, as determined by the EMMP.

Subsection (g) requires event managers of public equine events to submit all Declaration of Drugs Administered forms within 15 days of the last day of the event, and for saleyard managers of public horse sales within 15 days of the end of the month reported, which coincides with the timeline event managers are required to remit fees to the Department. As the Declaration of Drugs Administered forms may be used to determine if violations have occurred, it is necessary they are received by the EMMP timely.

Subsection (h) is necessary to clarify information provided on the Declaration of Drugs Administered form in conjunction with any other relevant evidence could be used by the Department in determining if a violation occurred. It is necessary that the Department adds this subsection because it states portions of the FAC section 24011 to make it easy for the public and industry to understand the importance of the drug declaration form with respect to compliance with the EMMP.

Authority and Reference citations are updated to reflect correct references to the FAC as a result of amendments to the section specifying the requirements for the declaration of drugs administered.

Section 1280.8

Subsections 1280.8 (c)(3)(A)(i) and (d)(4) reference use of the Declaration of Drugs Administered, Form 76-027 when a licensed veterinarian administers a therapeutic drug or medicine, as specified. The Department is amending references to the form in both subsections for consistency.

Section 1280.11

Section 1280.11 Table A: Equine Medication Monitoring Program Violations Matrix

The Department is amending references to the Title 3, CCR Section column to correctly identify the location in the regulations pertaining to a violation of sections 1280.1(b) and 1280.1(c).

TECHNICAL, THEORETICAL, AND EMPIRICAL STUDY, REPORT, OR SIMILAR DOCUMENT

No technical, theoretical, or empirical study, report, or similar document was used in formulating this proposal.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

This regulation does not mandate the use of specific technologies or equipment.

CONSIDERATION OF REASONABLE ALTERNATIVES

The Department has considered two alternatives to this proposal: 1) Not amend the regulations, or 2) Amend the existing forms incorporated by reference in the regulations. The Department is rejecting alternative number 1 because program forms are currently out of date and no longer meet program needs as written, and do not meet the requirements of the ADA. Alternative number 2 is rejected because the existing forms are incorporated by reference which does not allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant.

The Department determined that no reasonable alternative considered or that has otherwise been identified and brought the attention of the Department would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in

implementing the statutory policy or other provision of law. This proposal is necessary to allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

REASONABLE ALTERNATIVES THE DEPARTMENT HAS IDENTIFIED THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES

The Department has not identified any reasonable alternatives to the proposed action that would lessen any adverse impact on small businesses and no adverse impacts to small businesses are expected as a result of this proposed action. This proposal is necessary to allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

BENEFITS OF THIS REGULATORY ACTION

This proposal benefits the equine industry by promoting the safety of the horse and rider in competition and horses at public sales by prohibiting the misuse of drugs or medications that could fraudulently mask a disease, condition, or injury of the horse which could place the rider and/or the horse in jeopardy.

FINDINGS REGARDING EVIDENCE OF NO SIGNIFICANT ADVERSE IMPACT ON BUSINESS

No facts, evidence, documents, testimony, or other evidence of any significant adverse economic impact on business have been identified. This proposal is necessary to allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

This proposal does not duplicate or conflict with federal regulations because there are no federal regulations governing public equine events or sales. The Department is the sole State authority over specified public equine events and sales pursuant to Chapter 8 (commencing with section 24000) of Division 11 of the FAC.

ECONOMIC IMPACT ASSESSMENT

Business Impact

The Department has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in California.

The Department has made an initial determination that the proposed regulatory action will not have any significant statewide adverse economic impact directly affecting California businesses including the ability of California businesses to compete with businesses in other states.

The Department has made an initial determination that this regulatory proposal will impact the equine industry in California which may consist of persons and businesses required to register with the Department for any public horse events and sales held in California and affect persons and businesses choosing to participate in public horse events and sales in accordance with FAC section 24001, 24012, and 24015. The Department's proposal affects small businesses.

Persons/Businesses affected by this proposal:

- Persons required to register for equine events - California hosts approximately 1,300 registered equine events annually, ranging from small backyard schooling (practice) shows to internationally recognized endurance events, as well as other types of competition and public horse sales. This proposal will impact persons and businesses required to register with the Department for any public horse events and sales held in California in accordance with FAC sections 24001, 24012, and 24015.
- Persons choosing to participate in equine events - Equine events registered with the Department represent approximately 100,000 horse entries into competitions annually. For any equine that has received a prohibited substance, the

owner/trainer/exhibitor must complete and file with an event manager an Official Form for Declaration of Drugs Administered, Form 76-027, as specified. On average, the Department receives 350-400 completed drug declaration forms per year. This proposal will impact persons and businesses choosing to participate in public horse shows and sales in accordance with FAC sections 24001, 24012, and 24015.

Anticipated compliance requirements as a result of this proposal:

There are no new reporting requirements as a result of this proposal. This proposal amends section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant.

Benefits of the regulation to the health and welfare of California residents, worker safety, and the State's environment:

The Department is not aware of any specific benefits this proposal will have on the health of California residents, worker safety, or the State's environment. The Department believes this proposal benefits the welfare of California residents by protecting the economic health of the affected equine industry. This proposal is necessary to allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

Economic Impact Assessment Conclusion

The Department has made an initial determination that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states

by making it more costly to produce goods or services, and that it will not create or eliminate jobs or occupations. The proposal does not affect the creation of new businesses or the elimination of existing businesses within the State of California and does not affect the expansion of businesses currently doing business within the State of California. This proposal does not impact multiple industries. This proposal amends section 1280.1 to repeal the existing three (3) program forms used for the registration and assessment of equine events and sales, and for the reporting of medications used before and during equine events and sales which are currently incorporated by reference and identified by title, form number, and revision date. The Department is proposing to amend the language to replace the forms incorporated by reference with forms identified by title and form number and describe the substantive requirements and contents of each form in proposed sections 1280.1, 1280.2, and 1280.3. The Department also proposes to amend sections 1280.8 and 1280.11 to update references to forms used and subsection numbering. This proposal is necessary to allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant. Information provided on these forms is used to assist the Department in fulfilling its mandate of the protection of both the horse and rider in public horse shows and sales in accordance with FAC sections 24005, 24006, 24007, 24008, 24009, 24010, 24011, 24012, 24013, and 24015.

**ECONOMIC AND FISCAL IMPACT STATEMENT
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

ECONOMIC IMPACT STATEMENT

| | | | |
|---|---------------------------------|---|----------------------------------|
| ARTMENT NAME Food and Agriculture | CONTACT PERSON Thami Rodgers | EMAIL ADDRESS thamarah.rodgers@cdfa.ca.gov | TELEPHONE NUMBER 916-698-3276 |
| DESCRIPTIVE TITLE FROM NOTICE REGISTER OR FORM 400 Equine Medication Monitoring Program (EMMP) - Forms | | | NOTICE FILE NUMBER Z |

A. ESTIMATED PRIVATE SECTOR COST IMPACTS *Include calculations and assumptions in the rulemaking record.*

1. Check the appropriate box(es) below to indicate whether this regulation:

- | | |
|---|---|
| <input type="checkbox"/> a. Impacts business and/or employees | <input type="checkbox"/> e. Imposes reporting requirements |
| <input checked="" type="checkbox"/> b. Impacts small businesses | <input type="checkbox"/> f. Imposes prescriptive instead of performance |
| <input type="checkbox"/> c. Impacts jobs or occupations | <input checked="" type="checkbox"/> g. Impacts individuals |
| <input type="checkbox"/> d. Impacts California competitiveness | <input type="checkbox"/> h. None of the above (Explain below): |

If any box in Items 1 a through g is checked, complete this Economic Impact Statement.***If box in Item 1.h. is checked, complete the Fiscal Impact Statement as appropriate.***2. The Department of Food and Agriculture
(Agency/Department) estimates that the economic impact of this regulation (which includes the fiscal impact) is:

- Below \$10 million
 Between \$10 and \$25 million
 Between \$25 and \$50 million
 Over \$50 million *[If the economic impact is over \$50 million, agencies are required to submit a Standardized Regulatory Impact Assessment as specified in Government Code Section 11346.3(c)]*

3. Enter the total number of businesses impacted: See attachedDescribe the types of businesses (Include nonprofits): Persons or businesses that buy, sell, or exhibit equines for pleasure or profit.Enter the number or percentage of total businesses impacted that are small businesses: unknown4. Enter the number of businesses that will be created: 0 eliminated: 0Explain: This proposal does not affect the creation/elimination of jobs. It amends the regulations pertaining to forms used.5. Indicate the geographic extent of impacts: Statewide
 Local or regional (List areas): _____6. Enter the number of jobs created: 0 and eliminated: 0

Describe the types of jobs or occupations impacted: _____

This proposal does not affect the creation or elimination of jobs. It amends the regulations pertaining to forms used.7. Will the regulation affect the ability of California businesses to compete with other states by making it more costly to produce goods or services here? YES NO

If YES, explain briefly: _____

ECONOMIC AND FISCAL IMPACT STATEMENT

(REGULATIONS AND ORDERS)

STD. 399 (REV. 12/2013)

ECONOMIC IMPACT STATEMENT (CONTINUED)

ESTIMATED COSTS *Include calculations and assumptions in the rulemaking record.*

1. What are the total statewide dollar costs that businesses and individuals may incur to comply with this regulation over its lifetime? \$ 0
 - a. Initial costs for a small business: \$ 0 Annual ongoing costs: \$ 0 Years: _____
 - b. Initial costs for a typical business: \$ 0 Annual ongoing costs: \$ 0 Years: _____
 - c. Initial costs for an individual: \$ 0 Annual ongoing costs: \$ 0 Years: _____
 - d. Describe other economic costs that may occur: The Department is not aware of any other economic costs that may occur.

2. If multiple industries are impacted, enter the share of total costs for each industry: This proposal does not impact multiple industries.

3. If the regulation imposes reporting requirements, enter the annual costs a typical business may incur to comply with these requirements. *Include the dollar costs to do programming, record keeping, reporting, and other paperwork, whether or not the paperwork must be submitted.* \$ 0

4. Will this regulation directly impact housing costs? YES NO
If YES, enter the annual dollar cost per housing unit: \$ _____

Number of units: _____

5. Are there comparable Federal regulations? YES NO

Explain the need for State regulation given the existence or absence of Federal regulations: The Department is replacing existing program forms incorporated by reference with a description of the form contents in the regulation text.

Enter any additional costs to businesses and/or individuals that may be due to State - Federal differences: \$ 0

C. ESTIMATED BENEFITS *Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

1. Briefly summarize the benefits of the regulation, which may include among others, the health and welfare of California residents, worker safety and the State's environment: This proposal benefits the industry and public by promoting the safety of horse and rider in competitions and horses at public sales by prohibiting the misuse of drugs or medications. The Department is mandated to monitor equine events held statewide pursuant to FAC 24012.

2. Are the benefits the result of: specific statutory requirements, or goals developed by the agency based on broad statutory authority?

Explain: The Department is replacing program forms inc. by reference with a description of the form contents in the text.

3. What are the total statewide benefits from this regulation over its lifetime? \$ 0

4. Briefly describe any expansion of businesses currently doing business within the State of California that would result from this regulation: _____

This proposal will not expand any businesses currently doing business in this State.

D. ALTERNATIVES TO THE REGULATION *Include calculations and assumptions in the rulemaking record. Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

List alternatives considered and describe them below. If no alternatives were considered, explain why not: See attached.

**ECONOMIC AND FISCAL IMPACT STATEMENT
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

ECONOMIC IMPACT STATEMENT (CONTINUED)

Summarize the total statewide costs and benefits from this regulation and each alternative considered:

Regulation: Benefit: \$ 0 Cost: \$ 0

Alternative 1: Benefit: \$ 0 Cost: \$ 0

Alternative 2: Benefit: \$ 0 Cost: \$ 0

3. Briefly discuss any quantification issues that are relevant to a comparison of estimated costs and benefits for this regulation or alternatives: No quantification issues relevant to a comparison of estimated costs and benefits exist for this regulation or its alternatives.

4. Rulemaking law requires agencies to consider performance standards as an alternative, if a regulation mandates the use of specific technologies or equipment, or prescribes specific actions or procedures. Were performance standards considered to lower compliance costs? YES NO

Explain: This regulation does not mandate the use of specific technologies or equipment; however, the equine industry may.

E. MAJOR REGULATIONS Include calculations and assumptions in the rulemaking record.

California Environmental Protection Agency (Cal/EPA) boards, offices and departments are required to submit the following (per Health and Safety Code section 57005). Otherwise, skip to E4.

1. Will the estimated costs of this regulation to California business enterprises exceed \$10 million? YES NO

*If YES, complete E2. and E3
If NO, skip to E4*

Briefly describe each alternative, or combination of alternatives, for which a cost-effectiveness analysis was performed:

Alternative 1: _____

Alternative 2: _____

(Attach additional pages for other alternatives)

3. For the regulation, and each alternative just described, enter the estimated total cost and overall cost-effectiveness ratio:

Regulation: Total Cost \$ _____ Cost-effectiveness ratio: \$ _____

Alternative 1: Total Cost \$ _____ Cost-effectiveness ratio: \$ _____

Alternative 2: Total Cost \$ _____ Cost-effectiveness ratio: \$ _____

4. Will the regulation subject to OAL review have an estimated economic impact to business enterprises and individuals located in or doing business in California exceeding \$50 million in any 12-month period between the date the major regulation is estimated to be filed with the Secretary of State through 12 months after the major regulation is estimated to be fully implemented?

YES NO

If YES, agencies are required to submit a Standardized Regulatory Impact Assessment (SRIA) as specified in Government Code Section 11346.3(c) and to include the SRIA in the Initial Statement of Reasons.

5. Briefly describe the following:

The increase or decrease of investment in the State: N/A The Department is replacing existing program forms incorporated by reference with a description of the form contents in the regulation text.

The incentive for innovation in products, materials or processes: N/A The Department is replacing existing program forms incorporated by reference with a description of the form contents in the regulation text.

The benefits of the regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment and quality of life, among any other benefits identified by the agency: The Department is not aware of any benefits this proposal will have on the health of CA residents, worker safety, or the State's environment.

ECONOMIC AND FISCAL IMPACT STATEMENT

(REGULATIONS AND ORDERS)

STD. 399 (REV. 12/2013)

FISCAL IMPACT STATEMENT



FISCAL EFFECT ON LOCAL GOVERNMENT Indicate appropriate boxes 1 through 6 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.

1. Additional expenditures in the current State Fiscal Year which are reimbursable by the State. (Approximate)
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

\$ _____

a. Funding provided in _____

Budget Act of _____ or Chapter _____, Statutes of _____

b. Funding will be requested in the Governor's Budget Act of _____

Fiscal Year: _____

2. Additional expenditures in the current State Fiscal Year which are NOT reimbursable by the State. (Approximate)
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

\$ _____

Check reason(s) this regulation is not reimbursable and provide the appropriate information:

a. Implements the Federal mandate contained in _____

b. Implements the court mandate set forth by the _____ Court.

Case of: _____ vs. _____

c. Implements a mandate of the people of this State expressed in their approval of Proposition No. _____

Date of Election: _____

d. Issued only in response to a specific request from affected local entity(s).

Local entity(s) affected: _____

e. Will be fully financed from the fees, revenue, etc. from: _____

Authorized by Section: _____ of the _____ Code;

f. Provides for savings to each affected unit of local government which will, at a minimum, offset any additional costs to each;

g. Creates, eliminates, or changes the penalty for a new crime or infraction contained in _____

3. Annual Savings. (approximate)

\$ _____

4. No additional costs or savings. This regulation makes only technical, non-substantive or clarifying changes to current law regulations.

5. No fiscal impact exists. This regulation does not affect any local entity or program.

6. Other. Explain _____

ECONOMIC AND FISCAL IMPACT STATEMENT

(REGULATIONS AND ORDERS)

STD. 399 (REV. 12/2013)

FISCAL IMPACT STATEMENT (CONTINUED)

FISCAL EFFECT ON STATE GOVERNMENT Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.

1. Additional expenditures in the current State Fiscal Year. (Approximate)

\$ _____

It is anticipated that State agencies will:

a. Absorb these additional costs within their existing budgets and resources.

b. Increase the currently authorized budget level for the _____ Fiscal Year

2. Savings in the current State Fiscal Year. (Approximate)

\$ _____

3. No fiscal impact exists. This regulation does not affect any State agency or program.

4. Other. Explain The Department does not anticipate any costs associated with this proposal as it replaces existing program forms incorporated by reference with a description of the form contents in the regulation text.

C. FISCAL EFFECT ON FEDERAL FUNDING OF STATE PROGRAMS Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.

1. Additional expenditures in the current State Fiscal Year. (Approximate)

\$ _____

2. Savings in the current State Fiscal Year. (Approximate)

\$ _____

3. No fiscal impact exists. This regulation does not affect any federally funded State agency or program.

4. Other. Explain _____

FISCAL OFFICER SIGNATURE



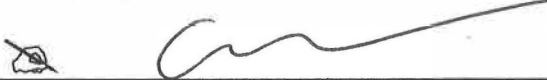
Nathan Johnson, Budget Officer

DATE

8/6/2020

The signature attests that the agency has completed the STD. 399 according to the instructions in SAM sections 6601-6616, and understands the impacts of the proposed rulemaking. State boards, offices, or departments not under an Agency Secretary must have the form signed by the highest ranking official in the organization.

AGENCY SECRETARY



Dr. Annette Jones, State Veterinarian & Director

DATE

August 28, 2020

Finance approval and signature is required when SAM sections 6601-6616 require completion of Fiscal Impact Statement in the STD. 399.

DEPARTMENT OF FINANCE PROGRAM BUDGET MANAGER



DATE

STD. 399 ECONOMIC AND FISCAL IMPACT – ATTACHMENT

ECONOMIC IMPACT STATEMENT

A. Estimated Private Sector Cost Impacts

3. This proposal will impact the equine industry in California which may include small businesses and individuals required to register with the Department of Food and Agriculture (Department) for any public horse events and sales held in California and persons choosing to participate in public horse events and sales. On average, the Equine Medication Monitoring Program (EMMP) registers 1,300 equine events annually (consisting of small businesses and individuals) representing approximately 100,000 horse entries (consisting of small businesses and individuals) into competitions. The Department receives approximately 350-400 drug declarations per year (consisting of small businesses and individuals) for any horse receiving a permissible or prohibited substance.

The 1300 event registrations, 100,00 horse entries, and 350-400 drug declarations represent businesses and individuals this proposal could potentially impact however does not accurately represent the *individual* number of businesses and individuals impacted because these numbers may include multiple registrations and entries by the same business and/or individual. As the Department does not maintain records of individual businesses and/or persons represented by these numbers, the number or percentage of businesses impacted by this proposal is unknown.

D. Alternatives to the Regulation

The Department has considered two alternatives to this proposal: 1) Not amend the regulations, or 2) Amend the existing forms incorporated by reference in the regulations. The Department is rejecting alternative number 1 because program forms are currently out of date and no longer meet program needs as written, and do not meet the requirements of the Americans with Disabilities Act (ADA). Alternative number 2 is rejected because the existing forms are incorporated by reference which does not allow the EMMP to revise forms as necessary to keep forms up to date and to ensure program forms are ADA compliant.