

**ADOPTED REGULATION OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

LCB File No. R104-23

EXPLANATION – Matter in *italics* is new; matter in brackets ~~omitted material~~ is material to be omitted.

AUTHORITY: §§ 1, 2, 4, 5, 7 and 8, NRS 439B.835 and 439B.875; §§ 3, 6, 9, 13-24 and 26, NRS 439B.875; § 10, NRS 439B.835, 439B.860 and 439B.875; §§ 11, 12 and 25, NRS 439B.835.

A REGULATION relating to health care; creating the All-Payer Claims Database Advisory Committee; prescribing the duties of the Advisory Committee; prescribing the manner in which the Department of Health and Human Services will collect data for inclusion in the all-payer claims database; establishing certain requirements for submitting data to the all-payer claims database; requiring certain entities to register with the Department; authorizing a data submitter to request a variance from certain requirements or an extension of time to submit data to the all-payer claims database; establishing procedures for the correction of erroneous data in the all-payer claims database; prescribing penalties for certain violations; prescribing the procedure for proceedings concerning the imposition of such penalties; and providing other matters properly relating thereto.

Legislative Counsel’s Digest:

Existing law requires the Department of Health and Human Services, to the extent that federal money is available, to: (1) establish an all-payer claims database of information relating to health insurance claims resulting from medical, dental or pharmacy benefits provided in this State; and (2) adopt regulations to establish an advisory committee to perform certain functions relating to the all-payer claims database. (NRS 439B.835) **Section 7** of this regulation defines the term “data submitter” to refer to entities that are required or authorized to submit data to the all-payer claims database. **Sections 2-6, 8 and 9** of this regulation define certain other terms for the purposes of this regulation.

Section 11 of this regulation establishes the All-Payer Claims Database Advisory Committee within the Department and prescribes certain rules governing the operation of the Advisory Committee. **Section 25** of this regulation provides for the appointment of certain members to the initial membership of the Advisory Committee. **Section 12** of this regulation sets forth the duties of the Advisory Committee, which include reporting to the Department annually concerning the quality, efficiency and cost of health care in this State. **Section 10** of this regulation interprets the term “cost of health care” for that purpose and for the purpose of a similar report that existing law requires the Department to submit to the Governor, the Patient Protection Commission and the Legislature. (NRS 439B.860)

Existing law: (1) requires certain entities that provide health coverage in this State to submit data to the all-payer claims database; and (2) provides that certain entities that provide health coverage in accordance with federal law may, but are not required to, submit data to the all-payer claims database. (NRS 439B.840) **Section 13** of this regulation provides that **sections 14-23** of this regulation, which relate to the submission of data to the all-payer claims database, apply to an entity that is not required to submit data to the all-payer claims database only to the extent that the entity elects to submit information to the all-payer claims database. **Section 14** provides that the Department will collect historical data for inclusion in the all-payer claims database in accordance with the provisions of existing law and this regulation. **Section 16** requires certain entities that provide health coverage to the residents of this State to annually register with the Department.

Existing law authorizes the Department to require certain entities that provide health coverage in this State and are not required by law to submit data to the all-payer claims database to, nonetheless, submit data to the all-payer claims database. (NRS 439B.875) **Section 17** accordingly requires Medicaid and the Children's Health Insurance Program to submit data to the all-payer claims database. **Section 17** also prescribes: (1) the types of data that a data submitter is required to submit to the all-payer claims database; and (2) procedures and deadlines for the submission of data to the all-payer claims database. **Section 15** adopts by reference a publication which prescribes the format for submitting data to the all-payer claims database, and **section 17** requires a data submitter to submit data to the all-payer claims database in that format. **Section 18** requires a data submitter to include certain information when submitting certain types of historical data to the all-payer claims database. **Section 19**: (1) requires a data submitter to de-identify the submitted data using a hashing algorithm recommended by the Federal Government; and (2) authorizes a data submitter to encrypt the data using Pretty Good Privacy encryption. **Section 26** of this regulation requires the Department to notify data submitters when the Department is prepared to accept data submissions. **Section 26** also prescribes the dates by which data submitters may and must begin submitting data.

Section 20 generally provides that the Department will only accept data submissions which pass certain validations for quality and are submitted by the deadline prescribed by **section 17**. **Section 21** establishes a procedure by which a data submitter may request a variance from the requirement for the validation of the quality of data while the data submitter completes or improves its data. **Section 22** establishes a procedure by which a data submitter may request an extension of time to submit data to the all-payer claims database.

Section 23 requires: (1) the administrator of the all-payer claims database to notify a data submitter of submitted historical data which contains errors; and (2) a data submitter that receives such notice to take certain measures to address the identified errors.

Existing law requires the Department to adopt regulations that prescribe administrative penalties to be assessed against any person or entity who violates certain statutory provisions governing the all-payer claims database or the regulations adopted pursuant thereto. (NRS 439B.875) **Section 24** of this regulation prescribes the penalties that the Department may impose. **Section 24** also establishes procedures for administrative proceedings concerning the imposition of such a penalty.

Section 1. Chapter 439B of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 24, inclusive, of this regulation.

Sec. 2. *As used in sections 2 to 24, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3 to 9, inclusive, of this regulation have the meanings ascribed to them in those sections.*

Sec. 3. *“Administrator” means the Department or the entity that is selected by the Department to manage the historical data in the all-payer claims database.*

Sec. 4. *“Advisory Committee” means the All-Payer Claims Database Advisory Committee created by section 11 of this regulation.*

Sec. 5. *“Claim” means any communication that is used to identify specific goods, items or services that are reimbursable by a third party, or which states income or an expense, and is or may be used by a third party to determine a rate of payment. The term includes, without limitation, a bill or line item for services.*

Sec. 6. *“Covered person” means a policyholder, subscriber, enrollee or other person covered by a third party.*

Sec. 7. 1. *“Data submitter” means:*

(a) An entity that is required by subsection 1 of NRS 439B.840 or subsection 1 of section 17 of this regulation to submit historical data to the all-payer claims database.

(b) An entity described in subsection 2 of NRS 439B.840 that elects to submit historical data to the all-payer claims database.

(c) An entity which submits historical data to the all-payer claims database on behalf of an entity described in paragraph (a) or (b), including, without limitation:

(1) A pharmacy benefit manager, as defined in NRS 683A.174, or other third party administrator; or

(2) An insurer that pays for behavioral health services which are excluded from other health care plans.

2. The term does not include an entity described in subsection 2 of NRS 439B.840 that does not elect to submit historical data to the all-payer claims database.

Sec. 8. *“Historical data” means the data described in subsection 2 of section 17 of this regulation.*

Sec. 9. *“Third party” means:*

- 1. A health carrier, as defined in NRS 439B.840;*
- 2. A governing body of a local governmental agency that provides health insurance through a self-insurance reserve fund pursuant to NRS 287.010;*
- 3. Medicaid;*
- 4. The Children’s Health Insurance Program;*
- 5. The Public Employees’ Benefits Program;*
- 6. A provider of health coverage for federal employees;*
- 7. A provider of health coverage that is subject to the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1101 et seq.; and*
- 8. The administrator of a Taft-Hartley trust formed pursuant to 29 U.S.C. § 186(c)(5).*

Sec. 10. *For the purposes of NRS 439B.860 and section 12 of this regulation, the Department will interpret “cost of health care” to mean the final payment made to a provider of health care by:*

1. An entity that is required by subsection 1 of NRS 439B.840 or subsection 1 of section 17 of this regulation to submit historical data to the all-payer claims database; or

2. An entity described in subsection 2 of NRS 439B.840 that elects to submit historical data to the all-payer claims database.

Sec. 11. *1. The All-Payer Claims Database Advisory Committee is hereby created within the Department.*

2. The Director shall appoint the members of the Advisory Committee, subject to the requirements of subsection 3, as follows:

(a) One member who is a provider of health care;

(b) One member who represents a health facility;

(c) One member who represents the Division of Public and Behavioral Health of the Department or a local board of health;

(d) One member who represents a health maintenance organization, as defined in NRS 695C.030;

(e) One member who represents a private insurer;

(f) One member who represents a nonprofit organization that represents consumers of health care services;

(g) One member who represents the data submitter that submitted the highest number of claims to the all-payer claims database during the immediately preceding 2 years; and

(h) One member who represents the data submitter that submitted the second highest number of claims to the all-payer claims database during the immediately preceding 2 years.

3. Each member of the Advisory Committee:

(a) Must be a resident of this State.

(b) Serves for a term of 2 years.

4. Members of the Advisory Committee serve without compensation, except that each member is entitled, while engaged in the business of the Advisory Committee, to the per diem allowance and travel expenses provided for state officers and employees generally, if money is available for that purpose.

5. The Director shall appoint a Chair of the Advisory Committee from among its members to hold office for a term of 1 year.

6. The Advisory Committee shall meet at least three times in each calendar year and may meet at other times upon the call of the Director or the Chair.

7. A majority of the members of the Advisory Committee constitutes a quorum for the transaction of business, and a majority of a quorum present at any meeting is sufficient for any official action taken by the Advisory Committee.

Sec. 12. *The Advisory Committee shall:*

1. Make recommendations to the Department concerning:

(a) Specifications for the collection of historical data for the all-payer claims database;

(b) The analysis and reporting of historical data in the all-payer claims database;

(c) The secure access to historical data in the all-payer claims database; and

(d) The secure release of historical data in the all-payer claims database pursuant to NRS 439B.800 to 439B.875, inclusive.

2. Annually submit to the Department a report concerning the quality, efficiency and cost of health care in this State.

3. Assist the Department in establishing and maintaining the all-payer claims database.

Sec. 13. *The provisions of sections 14 to 23, inclusive, of this regulation apply to an entity described in subsection 2 of NRS 439B.840 only to the extent that the entity elects to submit historical data to the all-payer claims database.*

Sec. 14. *The Department will collect historical data in accordance with the provisions of NRS 439B.800 to 439B.875, inclusive, and sections 14 to 23, inclusive, of this regulation.*

Sec. 15. *1. The Department hereby adopts by reference the All-Payer Claims Database - Common Data Layout in the form most recently published by the All-Payer Claims Database Council, unless the Department gives notice that the most recent revision is not suitable for this State pursuant to subsection 2. A copy of the All-Payer Claims Database - Common Data Layout may be obtained, free of charge, from the All-Payer Claims Database Council at the Internet website <https://www.apcdouncil.org/apcd-cdlm/download-apcd-cdlm>.*

2. The Department will review each revision of the All-Payer Claims Database - Common Data Layout adopted by reference in subsection 1 to ensure its suitability for this State. If the Department determines that a revision is not suitable for this State, the Department will hold a public hearing to review its determination within 12 months after the date of the publication of the revision and give notice of that hearing. If, after the hearing, the Department does not revise its determination, the Department will give notice within 30 days after the hearing that the revision is not suitable for this State. If the Department does not give such notice, the revision becomes part of the publication adopted by reference in subsection 1.

Sec. 16. *1. Not later than February 1 of each year, each third party that provides health coverage to residents of this State, including, without limitation, such a third party that is exempt pursuant to paragraph (a), (b) or (c) of subsection 1 of NRS 439B.840 from the requirement to submit data to the all-payer claims database, and each data submitter that will*

submit data to the all-payer claims database on behalf of a third party during that year shall register with the Department on a form prescribed by the Department.

2. The form must include, without limitation:

(a) The legal name of the registrant.

(b) The address of the registrant.

(c) For any insurer on whose behalf the registrant will submit historical data to the all-payer claims database:

(1) The company code assigned to the insurer by the National Association of Insurance Commissioners; and

(2) The federal employer identification number of the insurer.

(d) For at least two persons who represent the registrant, the following information:

(1) The first and last name of each person;

(2) The title of each person;

(3) A telephone number for each person;

(4) An electronic mail address for each person; and

(5) A mailing address for each person.

(e) A complete list of the types of historical data, as specified in subsection 2 of section 17 of this regulation, which the registrant is eligible to submit to the all-payer claims database.

(f) Any relationships between the registrant and:

(1) Any other entity on whose behalf the registrant will submit historical data to the all-payer claims database; or

(2) Any other data submitter that will submit historical data on behalf of an entity described in subparagraph (1).

Sec. 17. 1. *In addition to the entities described in subsection 1 of NRS 439B.840, Medicaid and the Children's Health Insurance Program shall submit historical data to the all-payer claims database.*

2. Each data submitter shall submit to the all-payer claims database in accordance with sections 14 to 23, inclusive, of this regulation the following historical data, to the extent applicable:

(a) Files of claims for covered medical services, including, without limitation, covered behavioral health services.

(b) Files of claims for covered pharmacy services.

(c) Files of claims for covered dental services.

(d) Files containing data relating to the eligibility for coverage and demographics of covered persons.

(e) Files containing data relating to providers of health care.

3. A data submitter shall submit historical data in the format prescribed by the All-Payer Claims Database - Common Data Layout, adopted by reference in section 15 of this regulation.

4. A data submitter shall submit historical data through:

(a) The portal for collection of historical data for the all-payer claims database which is managed by the administrator; or

(b) A secure file transfer protocol site which is hosted by the administrator.

5. Each data submitter shall submit historical data for each calendar quarter not later than the first business day of the second month following the end of that calendar quarter.

6. The first time a data submitter submits historical data to the all-payer claims database, the data submitter shall submit historical data for the 3 calendar years immediately preceding that initial submission of historical data.

Sec. 18. *1. Except as otherwise provided in subsection 2, a data submitter that submits historical data relating to covered medical services, dental services or pharmacy services shall include information on all service lines for every claim paid or encounter processed during the reporting period for which the historical data is submitted, regardless of the location where the service was provided.*

2. Except as otherwise provided in this subsection, a data submitter is not required to submit historical data pursuant to subsection 1 for a claim which is denied in its entirety. A data submitter shall submit historical data for a claim which was paid and reported to the all-payer claims database but is subsequently reversed or denied.

3. Files submitted to the all-payer claims database that contain historical data relating to providers of health care must include demographic data and other relevant data relating to each provider of health care who is referenced in historical data described in subsection 1 or 4, including, without limitation:

- (a) Primary care providers;*
- (b) Rendering providers;*
- (c) Billing providers;*
- (d) Referring providers;*
- (e) Attending providers;*
- (f) Prescribing providers; and*
- (g) Pharmacies.*

4. Files containing historical data relating to the eligibility for coverage and demographics of covered persons must include data for each covered person who resided in this State and was eligible for a defined set of benefits for 1 or more days within the reporting period. If a covered person is covered by more than one distinct policy, a record must be included for each policy. If the reporting period of the file spans multiple months, the covered person must be reported with one record per month of eligibility.

5. As used in this section, “encounter” means a covered service or group of services delivered by a provider to a covered person during a visit or as a result of a visit between the covered person and the provider.

Sec. 19. 1. *Each data submitter shall de-identify the historical data which it submits, including, without limitation, direct patient identifiers, by using a hashing algorithm prescribed and provided by the administrator. The administrator shall prescribe and provide to each data submitter a hashing algorithm which is recommended by the Federal Government.*

2. A data submitter may, but is not required to, encrypt using Pretty Good Privacy encryption the historical data which the data submitter submits.

Sec. 20. 1. *Except as otherwise provided in sections 21 and 22 of this regulation, the Department will only accept historical data which:*

(a) Passes the validation described in subsection 2; and

(b) Is submitted by the deadline prescribed by section 17 of this regulation for the submission of historical data.

2. When conducting a validation pursuant to paragraph (a) of subsection 1, the administrator shall use a process that meets the requirements of this section to ensure that the

format and content of the historical data submitted by data submitters are valid and complete.

The process must include, without limitation:

(a) A field-level audit conducted in accordance with subsection 3 when historical data is submitted;

(b) A quality audit conducted to determine whether the historical data meets the default threshold of reasonableness prescribed pursuant to paragraph (b) of subsection 4; and

(c) The consolidation of the data and a reasonableness, longitudinal and relational audit of the consolidated data to confirm whether the submission contains the appropriate amount of historical data for the number of persons covered by the data submitter.

3. A field-level audit conducted pursuant to paragraph (a) of subsection 2 must:

(a) Determine whether the historical data that is being audited is in the correct form and has been submitted using the hashing algorithm prescribed and provided pursuant to section 19 of this regulation; and

(b) Evaluate whether the field length and type, code values and the percentage of the fields that are filled meet the thresholds for completeness and content prescribed pursuant to paragraph (a) of subsection 4.

4. The administrator shall prescribe:

(a) For use in each field-level audit conducted pursuant to paragraph (a) of subsection 2, acceptable thresholds for the completeness and content of each element of historical data submitted by a data submitter; and

(b) For use in each quality audit conducted pursuant to paragraph (b) of subsection 2, a threshold for the reasonableness of the historical data, which may be expressed as a rate or a range.

5. When prescribing thresholds pursuant to subsection 4, the administrator shall initially assume that the acceptable threshold for each element is 100 percent but may establish a lower threshold upon determining that a threshold of 100 percent would be inappropriate for the element.

Sec. 21. 1. A data submitter may request a variance from the validation of the data required by section 20 of this regulation to allow the collection of historical data to proceed while the data submitter adds missing elements of data or makes other improvements to its data.

2. A request for a variance made pursuant to this section must:

(a) Be made through the portal for the collection of historical data for the all-payer claims database which is managed by the administrator; and

(b) Clearly identify:

(1) The nature of the issue or issues affecting the historical data;

(2) A plan for correcting the issues, if applicable; and

(3) The date by which the data submitter anticipates compliance with requirements for the submission of historical data.

3. The administrator shall:

(a) Review a request for a variance which satisfies the requirements of subsection 2; and

(b) Approve or deny the request not later than 5 days after the date on which the request was submitted.

4. A variance granted pursuant to this section is valid for a period of time specified by the administrator, not to exceed 1 year.

5. If the administrator denies a request for a variance:

(a) The data submitter that submitted the request shall comply with all applicable requirements to submit historical data to the all-payer claims database; and

(b) Neither the data submitter nor an entity on whose behalf the data submitter was required to submit historical data to the all-payer claims database is entitled to a hearing on the denial. The provisions of this paragraph do not affect the right of any person or entity to a hearing pursuant to section 24 of this regulation on a decision to impose an administrative penalty for any attendant failure to comply with the provisions of NRS 439B.800 to 439B.875, inclusive, and sections 2 to 24, inclusive, of this regulation.

Sec. 22. 1. *A data submitter may request an extension of time to submit historical data to the all-payer claims database for a period of time for which the data submitter is unable to comply with the deadline prescribed by section 17 of this regulation.*

2. A request for an extension made pursuant to this section must be submitted to the Department and include:

(a) A detailed explanation of the reason the data submitter is unable to comply with the requirement to submit historical data to the all-payer claims database by the deadline prescribed by section 17 of this regulation for the submission of historical data to be accepted for that calendar quarter; and

(b) The period of time for which the data submitter is requesting an extension, not to exceed 1 calendar quarter.

3. Except as otherwise provided in this subsection, a request for an extension made pursuant to this section must be submitted to the Department not less than 30 calendar days before the first deadline to submit historical data to the all-payer claims database to which the extension would apply. If a data submitter is unable to submit a request for an extension to the

Department on or before that date, the data submitter must notify the Department in writing as soon as the data submitter determines that an extension is necessary.

4. Upon receipt of a request for an extension submitted pursuant to this section not less than 30 calendar days before the first deadline to submit historical data to the all-payer claims database to which the extension would apply, the Department will suspend the requirement for the data submitter to submit historical data to the all-payer claims database while the Department determines whether to approve or deny the request. The Department may refuse to suspend that requirement if the request is submitted after that date.

5. Not later than 15 days after receipt of a request for an extension submitted pursuant to this section, the Department will issue a written determination to the data submitter notifying the data submitter whether the Department has approved or denied the request.

6. If the Department grants an extension, the written determination issued pursuant to subsection 5 must specify the period of time for which the extension has been granted.

7. If the Department denies a request for an extension made pursuant to this section:

(a) The data submitter that submitted the request shall comply with all applicable requirements to submit historical data to the all-payer claims database. If the denial is issued after the first deadline to submit historical data to the all-payer claims database to which the requested extension would have applied, the data submitter shall comply with all applicable requirements to submit historical data to the all-payer claims database within 15 calendar days after the date on which the written determination of denial was issued.

(b) Neither the data submitter nor any entity on whose behalf the data submitter was required to submit historical data to the all-payer claims database is entitled to a hearing on the denial. The provisions of this paragraph do not affect the right of any person or entity to a

hearing pursuant to section 24 of this regulation on a decision to impose an administrative penalty for any attendant failure to comply with the provisions of NRS 439B.800 to 439B.875, inclusive, and sections 2 to 24, inclusive, of this regulation.

Sec. 23. 1. *If the administrator determines that historical data which has previously been accepted contains an error that was not initially identified, the administrator shall notify the data submitter.*

2. A data submitter that is notified of an error pursuant to subsection 1 shall address the error identified by the administrator by either:

(a) Providing an explanation and, as necessary, documentation, to the administrator to demonstrate that the historical data is correct as initially submitted; or

(b) Correcting the error and resubmitting the historical data not later than 60 calendar days after the date on which the administrator notified the data submitter of the error.

Sec. 24. 1. *The Department may impose on a person or entity an administrative penalty for a violation of the provisions of NRS 439B.800 to 439B.875, inclusive, and sections 2 to 24, inclusive, of this regulation, as follows:*

(a) For the first violation within a 3-year period, an administrative penalty not to exceed \$2,500 for each day the person or entity remains in violation.

(b) For the second and each subsequent violation within a 3-year period, an administrative penalty not to exceed \$5,000 for each day the person or entity remains in violation.

2. The Department may impute a violation of the provisions of NRS 439B.800 to 439B.875, inclusive, and sections 2 to 24, inclusive, of this regulation by a data submitter to any entity on whose behalf the data submitter is required to submit historical data to the extent that the violation results in a violation of those provisions by that entity.

3. Upon deciding to impose an administrative penalty, the Department will provide written notice to the person or entity who is alleged to have committed the violation. The written notice must contain, without limitation:

(a) The determination of the Department, including, without limitation, each provision of law and regulatory provision which the person or entity is alleged to have violated; and

(b) Notification of the provisions of subsection 4.

4. Not later than 90 days after receiving notice of a decision to impose an administrative penalty pursuant to subsection 3, a person or entity may request a hearing by certified mail. If the Department receives a request for an administrative hearing that complies with the requirements of this subsection, the Department will:

(a) Appoint a hearing officer to conduct the hearing; and

(b) Notify the person or entity who requested the administrative hearing of the date, time, place and nature of the hearing.

5. The decision of a hearing officer appointed pursuant to subsection 4 must:

(a) Be in writing; and

(b) Detail the findings of the hearing officer and the support for those findings.

6. A decision by a hearing officer in an administrative hearing held pursuant to this section is a final decision for the purposes of judicial review.

Sec. 25. This regulation is hereby amended by adding thereto the following transitory language which has the force and effect of law but which will not be codified in the Nevada Administrative Code:

1. Notwithstanding the provisions of section 11 of this regulation, the Director of the Department of Health and Human Services shall appoint to the initial membership of the All-

Payer Claims Database Advisory Committee in place of the members described in paragraphs (g) and (h) of subsection 2 of section 11 of this regulation:

(a) One member who represents the data submitter that is responsible for the highest number of claims in this State during the immediately preceding 2 years, as reflected in the records of the Division of Insurance of the Department of Business and Industry; and

(b) One member who represents the data submitter that is responsible for the second-highest number of claims in this State during the immediately preceding 2 years, as reflected in the records of the Division of Insurance of the Department of Business and Industry.

2. As used in this section, “data submitter” has the meaning ascribed to it in section 7 of this regulation.

Sec. 26. This regulation is hereby amended by adding thereto the following transitory language which has the force and effect of law but which will not be codified in the Nevada Administrative Code:

1. The Department will provide written notice to data submitters when the Department is prepared to accept the submission of historical data in accordance with the requirements of this regulation.

2. Notwithstanding the provisions of section 17 of this regulation, a data submitter:

(a) May not submit historical data to the all-payer claims database until the first business day of the calendar quarter immediately following the calendar quarter during which the data submitter receives the notice described in subsection 1; and

(b) Is not required to submit historical data to the all-payer claims database until the first business day of the second month following the calendar quarter during which the data submitter receives the notice described in subsection 1.

3. As used in this section:

- (a) “All-payer claims database” has the meaning ascribed to it in NRS 439B.805.
- (b) “Data submitter” has the meaning ascribed to it in section 7 of this regulation.
- (c) “Department” means the Department of Health and Human Services.
- (d) “Historical data” has the meaning ascribed to it in section 8 of this regulation.