

Statistics Vital Health Statistics Series 13 (145):118.

21. HCUPnet, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, Rockville, MD (<http://www.ahrq.gov/data/hcup/hcupnet.htm>).

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Add § 201.24 to subpart A to read as follows:

§ 201.24 Labeling for systemic antibacterial drug products; required statements.

The labeling of all systemic drug products indicated to treat a bacterial infection, except a mycobacterial infection, must bear the following statements:

(a) At the beginning of the label, under the product name, the labeling must state:

Inappropriate use of (*insert name of antibacterial drug product*) may increase the prevalence of drug resistant microorganisms and may decrease the effectiveness of (*insert name of antibacterial drug product*) and related antimicrobial agents.

Use (*insert name of antibacterial drug product*) only to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms. See Indications and Usage section.

(b) In the “Clinical Pharmacology” section, the labeling must state:

Appropriate use of (*insert name of antibacterial drug product*) includes, where applicable, identification of the causative microorganism and determination of its susceptibility profile.

(c) In the “Indications and Usage” section, the labeling must state:

Local epidemiology and susceptibility patterns of the listed micro organisms should direct initial selection of (*insert name of antibacterial drug product*) for the treatment of the indications listed below. Because of changing susceptibility patterns, definitive therapy should be guided by the results of susceptibility testing of the isolated pathogens.

(d) In the “Precautions” section, under the “General” subsection, the labeling must state:

Inappropriate use of (*insert name of antibacterial drug product*) may increase the prevalence of drug resistant microorganisms and may decrease the future effectiveness of (*insert name of antibacterial drug product*) and related antimicrobial agents.

(*Insert name of antibacterial drug product*) should only be used to treat infections that are proven or strongly suspected to be caused by susceptible microorganisms. See Indications and Usage section.

(e) In the “Precautions” section, under the “Information for patients” subsection, the labeling must state:

Patients should be counseled that (*insert name of antibacterial drug product*) should only be used to treat bacterial infections. It does not treat viral infections (e.g., the common cold).

Patients should also be told that the medication should be taken exactly as directed. Skipping doses and not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop that will not be treatable by (*insert name of antibacterial drug product*) in the future.

Dated: August 25, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–24007 Filed 9–18–00; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

39 CFR Part 111

Address Sequencing Service

AGENCY: Postal Service.

ACTION: Proposed rule with request for comment.

SUMMARY: This proposed rule amends section A920 of the Domestic Mail Manual (DMM) to enhance customer service and to provide notice of new safeguards to protect the ownership of customer address lists.

DATES: Comments must be received on or before October 19, 2000.

ADDRESSES: Written comments should be sent to Manager, Address Management, USPS, 6060 Primacy Pkwy, Ste 201, Memphis, TN 38188–0001. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at the above address.

FOR FURTHER INFORMATION CONTACT:

DeWitt Crawford, (901) 681–4612, or Susan Hawes, (901) 681–4661.

SUPPLEMENTARY INFORMATION: The manual address card sequencing process that has been available for many years has become too labor intensive and expensive for some mailers to maintain. An increasing number of customers have requested the adoption of a more efficient and cost-effective procedure for the sequencing of address lists. In response, the USPS is proposing an electronic address sequencing service for those customers who want to discontinue the production and processing of manual address cards. This proposal is an outgrowth of meetings the USPS conducted with saturation mailer groups and the Mailers Technical Advisory Committee (MTAC).

To ensure the integrity of the qualification process for the electronic sequencing service, all USPS-qualified walk sequence address files will contain seeded addresses known only to the list owner and the USPS. This will help guard against the fraudulent submission of rented lists for qualification. If a request for sequencing contains a seeded address, and all known possibilities of fraud cannot be ruled out, the request will be denied and the owner of the seeded address and the Postal Inspection Service will be notified. Notification will include requester's company name, ZIP Code, and level of address group requested for qualification.

Customers will be allowed three attempts to qualify a ZIP Code within a six-month period. Failure to qualify within this time frame will result in a suspension of one year from further attempts to qualify the ZIP Code.

To protect the integrity of customer address lists, and to add a level of security, all customer requests for DMM A920 card and electronic processing will be posted for 90 days on a password-secured USPS Address Sequencing Service Web site. Company name, ZIP Code, and requested address groups will be listed. This will enable USPS-qualified list owners to monitor possible misuse of their rented or leased address lists. Only USPS-qualified list owners will be able to access the Web site.

Summary of Proposed Change

Proposed DMM sections A920.1.0 through A920.6.4 provide an electronic address sequencing service for those customers who want to discontinue the production and processing of manual address cards.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 is revised to read as follows:

Authority: 5 U.S.C. 552 (a); 39 U.S.C. 101, 401, 403, 404, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

2. Amend the following section of the Domestic Mail Manual (DMM) as follows:

A Addressing

* * * * *

A900 Customer Support

* * * * *

A920 Address Sequencing Services

[Amend 1.0 to add electronic file options to read as follows:]

1.0 SERVICE LEVELS

The USPS provides the following levels of manual or electronic address sequencing service for city carrier routes, rural routes, highway contract routes, and post office box sections:

- a. Sequencing of address cards or electronic address files.
- b. Sequencing of address cards or electronic address files, plus inserting blank cards for missing addresses or missing sequence numbers for the addresses missing from the electronic files.
- c. Sequencing of address cards or electronic address files, plus inserting cards with addresses for missing or new addresses, or inserting addresses into electronic files for missing or new addresses.

[Revise the heading of 2.0 to read as follows:]

2.0 CARD OR FILE PREPARATION AND SUBMISSION

[Revise 2.1 to read as follows:]

2.1 Color and Size

When submitting cards, all address cards must be made of white or buff-colored card stock and identical in size (5 to 8⁵/₁₆ inches long and 2¹/₄ to 4¹/₄ inches high). Blank cards for missing and/or new addresses must be of the same size as the submitted address cards but of a different color. A customer must provide enough blank cards to equal at least 10 percent of the number of address cards submitted.

[Revise 2.2 to read as follows:]

2.2 Limitation

The customer must not submit address cards or an address file in

excess of 110 percent of the possible deliveries for a specific 5-digit ZIP Code delivery area. Customers requesting the service level in A920.1.0c will be allowed three attempts to qualify a ZIP Code for the service within a 6-month period. Failure to qualify within 6 months will result in a suspension of 1 year for any additional attempts to qualify the ZIP Code.

[Revise 2.3 to read as follows:]

2.3 Addressing Format

Addressing format is specific to the media being used.

a. Card Processing—Cards must be faced in the same direction and bear only one address each. The customer's current address information must be computer-generated, typed, or printed along the top of the card. The address must be within 1 inch from the top edge of the card in about the same location on each card submitted. Each card must include a complete address except for the ZIP Code, which is optional. Street designators may be abbreviated as shown in Publication 28, Postal Addressing Standards. When sequence cards are used to obtain address sequencing information for post office boxes, the box section number must be substituted for the carrier route number (if shown).

b. Electronic Processing—The customer must submit address files on electronic media, as described by the USPS. Call the National Customer Support Center at 800–331–5747 for a copy of the required format.

[Revise the first sentence of 2.4 and add second sentence to read as follows:]

2.4 Header Cards

When submitting address cards customers must provide carrier route header cards, prepared with standard 80-column computer card stock (or another size as described above). The header cards must be typed, computer-generated, or printed by the customer.

* * *

[Revise 2.5 to read as follows:]

2.5 Delivery Unit Summary

A Delivery Unit Summary must be typed, computer-generated, or printed and provided by the customer for card processing. A printed copy or electronic file will be acceptable for address file submissions. When submitting address cards, an original and two copies must be submitted for each 5-digit ZIP Code delivery area. When submitting an address file, an original and two copies of a printed form or one electronic file must be submitted for each 5-digit ZIP Code delivery area. This form, used by the USPS to provide summary

information to the customer, is necessary for calculating total charges for the service level provided. The original is returned to the customer with the cards as the customer's bill. Examples of the required format for the Delivery Unit Summary can be obtained from the National Customer Support Center (see G043).

[Revise the first sentence of 2.6 to read as follows:]

2.6 5-Digit ZIP Codes

When submitting address cards, the cards for each 5-digit ZIP Code area must be placed in separate containers, each with an envelope affixed containing a packing list and Delivery Unit Summary sheets for that 5-digit ZIP Code area. * * *

[Revise 2.7 to read as follows:]

2.7 Submitting Cards or Electronic Files

The designated place for submission of addresses for sequencing depends on the type of media used.

a. Card Processing—The customer must submit the containers of address cards to the district manager of Address Management Systems for carrier routes within the corresponding district. (Exception: Address cards only for addresses in the city where the customer is located may be submitted to the postmaster of that city for sequencing and correction.) Unless otherwise directed, the customer must address containers of address cards to: MANAGER ADDRESS MANAGEMENT SYSTEMS

UNITED STATES POSTAL SERVICE
[STREET ADDRESS]
[CITY/STATE/ZIP+4]

b. Electronic Processing—The customer must submit address files on electronic media, as described by the USPS, to:

COMPUTERIZED DELIVERY
SEQUENCING DEPARTMENT
NATIONAL CUSTOMER SUPPORT
CENTER

UNITED STATES POSTAL SERVICE
6060 PRIMACY PKWY STE 201
MEMPHIS TN 38188–0001

[Revise 2.8 by adding the following after the first sentence:]

2.8 Postage

* * * Address files can be mailed at the appropriate rate or be electronically transmitted, as determined by the USPS, to the National Customer Support Center. * * *

[Revise 2.9 to read as follows:]

2.9 USPS Sequencing

Unsequenced address cards received at post offices or unsequenced address

files received at the National Customer Support Center will be arranged in sequence of carrier route delivery without charge. Cards with incorrect or undeliverable addresses are removed from carrier route bundles, bundled separately, and returned to the customer. When address files are submitted, incorrect or undeliverable addresses are removed from the original file and returned as a separate file.

[Revise the heading and first sentence of 2.10 to read as follows:]

2.10 USPS Time Limits and Billing

The post office or the National Customer Support Center, whichever performs the service, returns the cards or address file and the bill for applicable charges to the customer within 15 working days after receiving a properly prepared request for address sequencing. This time limit does not apply to cards received between November 16 and January 1, which are sequenced as promptly as possible.

* * *

[Revise 2.11 to read as follows:]

2.11 Seasonal Addresses

Under all service levels, correct addresses subject to seasonal occupancy, but which do not indicate seasonal treatment, will be identified with an "S" on cards or a flag on address files. If the address is included in a series such as those used for apartment buildings, trailer parks, and seasonal delivery areas in general, the appropriate "seasonal" indicator box is checked on the card or flagged on the address file. When correct address cards or address files are submitted that are not subject to seasonal occupancy, but include seasonal treatment notations, the seasonal indicator is marked out on cards or left blank on address files. For cards, a rubber band is placed around the card to identify it before it is put in carrier route sequence order in the returned deck of cards. No charge is assessed for this service.

[Revise the heading of 3.0 to read as follows:]

3.0 SEQUENCING CARDS WITH BLANKS FOR MISSING ADDRESSES OR SEQUENCING ADDRESS FILES WITH MISSING SEQUENCE NUMBERS

[Revise 3.1 to read as follows:]

3.1 USPS Sequencing

USPS employees at post offices (for cards) or the National Customer Support Center (for address files) arrange unsequenced addresses in sequence of carrier route delivery without charge and remove incorrect or undeliverable addresses. Cards are bundled separately

for return to the customer, with blank cards inserted for each existing address that is not included in the customer's cards. Address files are returned with missing sequence numbers inserted. (If several addresses in a series are missing, a single blank card is inserted for the series showing the number of missing addresses. For address files a series of missing sequence numbers is inserted identifying the number of missing addresses.)

[Revise 3.2 to read as follows:]

3.2 USPS Time Limits and Billing

The post office or the National Customer Support Center, whichever performs the service, returns the cards or address file along with a bill for applicable charges to the customer within 15 working days after receiving a properly prepared request for address sequencing. This time limit does not apply to cards received between November 16 and January 1, which are sequenced as promptly as possible.

[Revise heading of 4.0 to read as follows:]

4.0 SEQUENCING WITH ADDRESS CARDS OR ADDRESS FILE WITH ADDRESSES ADDED FOR MISSING AND NEW ADDRESSES

[Revise 4.1 to read as follows:]

4.1 USPS Sequencing

USPS employees at post offices (for cards) or the National Customer Support Center (for address files) arrange unsequenced addresses in sequence of carrier route delivery without charge and remove incorrect or undeliverable addresses. New or missing addresses (including rural address conversions to city delivery) are added for each existing address that is not included in the customer's cards or address file. Cards are bundled separately for return to the customer. An address file is returned as a separate file.

[Revise 4.2 to read as follows:]

4.2 Separate Address Groups

Separate groups of address cards must be submitted for the addresses in each 5-digit ZIP Code delivery area: city carrier (residential addresses only); city carrier (business addresses only); city carrier (combination of residential and business addresses); rural and highway contract route addresses; or post office box addresses (whether business, residential, or a combination). If submitting an electronic address file, a single file meeting the same requirements is acceptable. Each group must be accompanied by a statement showing:

- a. Types of addresses (i.e., residential, business, or a combination).
- b. Number of addresses on the cards or in the address file.
- c. Name, mailing address, and telephone number of the list owner or agent.

* * * * *

[Revise 4.4 to read as follows:]

4.4 Address Percentage

For the 5-digit ZIP Code area, the mailing list that the cards or address file represent must contain 90 percent of all possible residential or business city carrier addresses for addresses in the respective address group, 90 percent of all city carrier addresses for addresses in a combination residential/business address group, or 90 percent of all possible deliveries for addresses in rural/highway contract route and post office box groups.

* * * * *

[Revise the heading and the first sentence of 4.6 to read as follows:]

4.6 Resubmitting Cards or Address File

Customers must monitor community growth and determine when address cards or address files need to be submitted for resequencing to maintain the 90 percent eligibility level of address coverage.

5.0 SERVICE CHARGES

[Revise the first sentence of 5.1 to read as follows:]

5.1 Basic Service

For sequencing of address cards or address file, the applicable fee is charged for each address card or address that is removed because of an incorrect or undeliverable address. * * *

[Revise 5.2 to read as follows:]

5.2 Blanks for Missing Addresses

For sequencing of address cards or address file with total possible deliveries shown, the applicable fee is charged for each address card or address that is removed because it is incorrect or undeliverable. No charge is assessed for the insertion of blank cards or missing sequence numbers (for address files) showing the range of missing addresses in a submitted list.

[Revise the first sentence of 5.3 to read as follows:]

5.3 Missing or New Addresses

For sequencing of address cards or address file with missing or new addresses added, the applicable fee is charged for each address card or address that is removed because it is incorrect or undeliverable, and for each address

(possible delivery) that is added to the customer's list. * * *

* * * * *

[Amend 5.5 by revising paragraph a to read as follows:]

5.5 Free Services

* * * * *

a. If the customer includes a rural address (box number) in a deck of cards or address file submitted for sequencing, and a street address is assigned to that box number so it can be served on a city delivery route, a correct address card or address is included at no charge.

* * * * *

6.0 SUBMITTING PROPERLY SEQUENCED MAILINGS

[Revise the first sentence of 6.1 to read as follows:]

6.1 Customer Responsibility

The customer must ensure that mailings are prepared in correct carrier route delivery sequence and resequence cards or an address file when necessary. * * *

[Revise 6.2 to read as follows:]

6.2 Changes

If delivery changes occur that affect delivery sequence, but do not cause scheme changes, the customer is notified in writing and must then submit cards or an address file for the affected routes or the complete ZIP Code for resequencing.

[Revise the third sentence of 6.3 to read as follow:]

6.3 Out-of-Sequence Mailing

* * * If the customer does not take corrective action, the USPS gives written notice that the customer is no longer allowed to submit address cards to the post office or address files to the National Customer Support Center for sequencing. * * *

[Revise 6.4 to read as follows:]

6.4 Reinstatement

Generally, a customer denied address card or address file sequencing service for a specific ZIP Code may not submit cards for sequencing at the post office or submit address files for sequencing at the National Customer Support Center where that sequencing service was terminated for 1 year after the effective date of termination. After that time, the customer is again authorized to submit the ZIP Code address cards (to the post office) or an address file (to the National Customer Support Center) for sequencing. At any time during the year after termination of service, the customer may renew the submission if the postmaster (for address cards) or the

National Customer Support Center (for address files) is convinced that the customer has taken all necessary action to correct the past errors.

An appropriate amendment to 39 CFR part 111 to reflect these changes will be published if the proposal is adopted.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 00-23658 Filed 9-18-00; 8:45 am]

BILLING CODE 7710-12-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 385 and 386

[Docket No. FMCSA-00-7332]

RIN 2126-AA54

Sanctions Against Motor Carriers, Brokers, and Freight Forwarders for Failure to Pay Civil Penalties

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FMCSA proposes to implement section 206 of the Motor Carrier Safety Improvement Act of 1999 (MCSIA) by amending the penalty provisions of the rules of practice of the Federal Motor Carrier Safety Regulations (FMCSRs). This action would prohibit a motor carrier that does not pay civil penalties assessed by the FMCSA, or that does not arrange and abide by its payment agreements, from operating in interstate commerce. Furthermore, the registration of a broker, freight forwarder, or for-hire motor carrier that fails to pay a civil penalty would be suspended. The prohibition would begin on the 91st day after the payment date specified in the final agency order or on the 91st day after the due date of a missed payment arranged in a payment plan. Motor carriers that continue to operate would be subject to additional penalties, including revocation of their registrations. However, the prohibition would not apply to anyone who is unable to pay a civil penalty because the person is a debtor in a case under chapter 11 of the Bankruptcy Code.

DATES: Comments must be received on or before October 19, 2000.

ADDRESSES: Your signed, written comments must refer to the docket number appearing at the top of this document and you must submit the comments to the Docket Clerk, U.S.

DOT Dockets, Room PL-401, 400 Seventh Street, SW., Washington, DC 20590-0001.

All comments received will be available for examination at the above address between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

All comments will be available for examination using the docket number appearing at the top of this document in the docket room at the above address. The FMCSA will file comments received after the comment closing date in the docket and will consider late comments to the extent practicable. The FMCSA may, however, issue a final rule at any time after the close of the comment period. In addition to late comments, the FMCSA will also continue to file, in the docket, relevant information becoming available after the comment closing date, and interested persons should continue to examine the docket for new material.

FOR FURTHER INFORMATION CONTACT: Ms. Deborah M. Freund, Office of Bus and Truck Standards and Operations, (202) 366-4009, Federal Motor Carrier Safety Administration, 400 Seventh Street, SW., Washington, DC 20590-0001; or Mr. Charles Medalen, Office of the Chief Counsel, HCC-20, (202) 366-1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590-0001. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users may access all comments received by the U.S. DOT Dockets, Room PL-401, by using the universal resource locator (URL): <http://dms.dot.gov>. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512-1661. Internet users may reach the Office of the Federal Register's home page at <http://www.nara.gov/fedreg> and the Government Printing Office's database at <http://www.access.gpo.gov/nara>.

Background

Section 206 of the Motor Carrier Safety Improvement Act of 1999 (MCSIA)(Public Law 106-159, 113 Stat.