## 9505.0340 PHARMACY SERVICES.

- Subpart 1. **Definitions.** The following terms used in this part have the meanings given to them.
- A. "Actual acquisition cost" means the cost to the provider including quantity and other special discounts except time and cash discounts.
- B. "Compounded prescription" means a prescription prepared under part 6800.3100.
- C. "Dispensing fee" means the amount allowed under the medical assistance program as payment for the pharmacy service in dispensing the prescribed drug.
- D. "Maintenance drug" means a prescribed drug that is used by a particular recipient for a period greater than two consecutive months.
- E. "Pharmacist" means a person licensed under Minnesota Statutes, chapter 151, to provide services within the scope of pharmacy practice.
- F. "Pharmacy" means an entity registered by the Minnesota Board of Pharmacy under Minnesota Statutes, chapter 151.
- G. "Pharmacy service" means the dispensing of drugs under Minnesota Statutes, chapter 151 or by a physician under subpart 2, item B.
- H. "Prescribed drug" means a drug as defined in Minnesota Statutes, section 151.01, subdivision 5, and ordered by a practitioner.
- I. "Practitioner" means a physician, osteopathic physician, dentist, or podiatrist licensed under Minnesota Statutes or the laws of another state or Canadian province to prescribe drugs within the scope of his or her profession.
- J. "Usual and customary charge" refers to the meaning in part 9505.0175, subpart 49, whether the drug is purchased by prescription or over the counter, in bulk, or unit dose packaging. However, if a provider's pharmacy is not accessible to, or frequented by, the general public, or if the over the counter drug is not on display for sale to the general public, then the usual and customary charge for the over the counter drug shall be the actual acquisition cost of the product plus a 50 percent markup based on the actual acquisition cost. In this event, this calculated amount must be used in billing the department for an over the counter drug.

Amounts paid in full or in part by third-party payers shall be included in the calculation of the usual and customary charge only if a third-party payer constitutes 51 percent or more of the pharmacy's business based on the number of prescriptions filled by the pharmacy on a quarterly basis.

- Subp. 2. **Eligible providers.** The following providers are eligible for payment under the medical assistance program for dispensing prescribed drugs:
  - A. a pharmacy that is licensed by the Minnesota Board of Pharmacy;
  - B. an out-of-state vendor under part 9505.0195, subpart 9; and
- C. a physician located in a local trade area where there is no enrolled pharmacy. The physician to be eligible for payment shall personally dispense the prescribed drug according to Minnesota Statutes, section 151.37, and shall adhere to the labeling requirements of the Minnesota Board of Pharmacy.
- Subp. 3. **Payment limitations.** Payments for pharmacy services under the medical assistance program are limited as follows.
- A. The prescribed drug must be a drug or compounded prescription that is approved by the commissioner for inclusion in the department's drug formulary. The drug formulary committee established under Minnesota Statutes, sections 256B.02, subdivision 8 and 256B.0625, shall recommend to the commissioner the inclusion of a drug or compounded prescription in the drug formulary. The commissioner may add or delete a drug or compounded prescription from the drug formulary. A provider, recipient, or seller of prescription drugs or compounded prescriptions may apply to the department on the form specified in the drug formulary to add or delete a drug from the drug formulary.
- B. A prescribed drug must be dispensed in the quantity specified on the prescription unless the pharmacy is using unit dose dispensing or the specified quantity is not available in the pharmacy when the prescription is dispensed. Only one dispensing fee is allowed for dispensing the quantity specified on the prescription.
- C. The dispensed quantity of a prescribed drug must not exceed a three month supply unless prior authorization is obtained by the pharmacist or dispensing physician.
- D. An initial or refill prescription for a maintenance drug shall be dispensed in not less than a 30 day supply unless the pharmacy is using unit dose dispensing. No additional dispensing fee shall be paid until that quantity is used by the recipient.
- E. Except as in item F, the dispensing fee billed by or paid to a particular pharmacy or dispensing physician for a maintenance drug for a recipient is limited to one fee per 30-day supply.
- F. More than one dispensing fee per calendar month for a maintenance drug for a recipient is allowed if the record kept by the pharmacist or dispensing physician documents that there is a significant chance of overdosage by the recipient if a larger quantity of drug is dispensed, and if the pharmacist or dispensing physician writes a statement of this reason on the prescription.

- G. A refill of a prescription must be authorized by the practitioner. Refilled prescriptions must be documented in the prescription file, initialed by the pharmacist who refills the prescription, and approved by the practitioner as consistent with accepted pharmacy practice under Minnesota Statutes, chapters 151 and 152.
- H. A generically equivalent drug as defined in Minnesota Statutes, section 151.21, subdivision 2, must be dispensed in place of the prescribed drug if:
- (1) the generically equivalent drug is approved by the United States Food and Drug Administration and is also determined as therapeutically equivalent by the United States Food and Drug Administration; and
- (2) in the professional judgment of the pharmacist, the substituted drug is therapeutically equivalent to the prescribed drug; and
- (3) the charge for the substituted generically equivalent drug does not exceed the charge for the drug originally prescribed.

However, a substitution must not be made if the practitioner has written in his or her own handwriting "Dispense as Written" or "DAW" on the prescription, as provided in the Minnesota Drug Selection Act, Minnesota Statutes, section 151.21. The pharmacy must notify the recipient and the department when a generically equivalent drug is dispensed. The notice to the recipient may be given orally or by appropriate labeling on the prescription's container. The notice to the department must be by appropriate billing codes.

- I. Unless otherwise established by the legislature, the amount of the dispensing fee shall be set by the commissioner. The fee shall be the lower of the average dispensing fee set by third-party payers in the state or the average fee determined by a cost of operation survey of pharmacy providers reduced by the yearly Consumer Price Index (urban) for the Minneapolis-Saint Paul area to the base year set by the legislature for other provider fees.
  - J. The cost of delivering a drug is not a covered service.
- Subp. 4. **Payment limitations; unit dose dispensing.** Drugs dispensed under unit dose dispensing in accordance with part 6800.3750 shall be subject to the medical assistance payment limitations in items A to C.
- A. Dispensing fees for drugs dispensed in unit dose packaging as specified in part 6800.3750 shall not be billed or paid more often than once per calendar month or when a minimum of 30 dosage units have been dispensed, whichever results in the lesser number of dispensing fees, regardless of the type of unit dose system used by the pharmacy or the number of times during the month that the pharmacist dispenses the drug. If the recipient's drug supply is dispensed in small increments during the calendar month, the pharmacy must keep a written record of each dispensing act that shows the date, National Drug Code, and the quantity of the drug dispensed.

- B. Only one dispensing fee per calendar month shall be billed or paid for each maintenance drug regardless of the type of unit dose system used by the pharmacy or the number of times during the month that the pharmacist dispenses the drug. If the recipient's drug supply is dispensed in small increments during the month, the pharmacy must keep a written record of each dispensing act that shows the date, National Drug Code, and the quantity of drug dispensed.
- C. The date of dispensing must be reported as the date of service on the claim to the department except when the recipient's drug supply is dispensed in small increments during the month. For this exception, the last dispensing date of the calendar month must be reported on the claim to the department as the date of service. In the case of an exception, the quantity of drug dispensed must be reported as the cumulative total dispensed during the month or a minimum amount as required in item A, whichever results in the lesser number of dispensing fees.
- Subp. 5. **Return of drugs.** Drugs dispensed in unit dose packaging under part 6800.3750, subpart 2, shall be returned to a pharmacy as specified in items A to C when the recipient no longer uses the drug.
- A. A provider of pharmacy services using a unit dose system must comply with part 6800.2700.
- B. A long-term care facility must return unused drugs dispensed in unit dose packaging to the provider that dispensed the drugs.
- C. The provider that receives the returned drugs must repay medical assistance the amount billed to the department as the cost of the drug.
- Subp. 6. **Billing procedure.** Providers of pharmacy services shall bill the department their usual and customary charge for the dispensed drug. All pharmacy claims submitted to the department must identify the National Drug Code printed on the container from which the prescription is actually filled. If a National Drug Code is not printed on the manufacturer's container from which the prescription is filled, the claim must name the code required by the department under the drug formulary, or identify either the generic or brand name of the drug. Except as provided in subpart 4, item C, the date reported as the date dispensed must be the date on which the quantity reported on the billing claim was dispensed.
- Subp. 7. **Maximum payment for prescribed drugs.** The maximum payment for a prescribed drug or compounded prescription under the medical assistance program must be the lowest of the following rates:
- A. The maximum allowable cost for a drug established by the department or the Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services plus a dispensing fee.

B. The actual acquisition cost for a drug plus a dispensing fee.

C. The pharmacy's usual and customary charge.

Statutory Authority: MS s 256B.04

**History:** 12 SR 624; L 1988 c 689 art 2 s 268; L 2002 c 277 s 32; L 2016 c 119 s 7

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