RULES OF

Department of Social Services

Division 70—MO HealthNet Division

Chapter 20—Pharmacy Program

TITLE 13 — DEPARTMENT OF SOCIAL SERVICES
Division 70 — MO HealthNet Division
Chapter 20 — Pharmacy Program

13 CSR 70-20.010 Participating Drug Vendors
(Rescinded September 30, 2018)

AUTHORITY: section 207.020, RSMo 1986. This rule was previously filed as 13 CSR 40-81.011. Original rule filed Nov. 13, 1978, effective Feb. 11, 1979. Rescinded: Filed March 2, 2018, effective Sept. 30, 2018.

13 CSR 70-20.030 Drugs Covered by the MO HealthNet Pharmacy Program

PURPOSE: This rule implements recent changes in drug coverage as mandated by the Centers for Medicare & Medicaid Services (CMS).

(1) Drugs covered under the MO HealthNet Pharmacy Program must meet the definition of a covered outpatient drug as defined in the Social Security Act, section 1927(k)(2) and section 1927(k)(3), as amended.

(2) Participating Manufacturers — The MO HealthNet Division identifies those manufacturers who have entered into a rebate agreement according to the Social Security Act, section 1927(a)(1), as amended. All products marketed by participating manufacturers are reimbursable, with the following exceptions: those products identified as Drug Efficacy Study Implementation (DESI) drugs by the federal Food and Drug Administration (FDA); products considered by the federal FDA to be similar, identical or related to a DESI product; products identified in 13 CSR 70-20.031; and products not meeting the definition of drug in sections 505, 506, and 507 of the federal Food, Drug and Cosmetic Act.

AUTHORITY: sections 208.152, 208.153, 208.201, and 660.017, RSMo 2016. This rule was previously filed as 13 CSR 40-81.010. Original rule filed Jan. 21, 1964, effective Jan. 31, 1964. Amended: Filed March 30, 1964, effective April 10, 1964. Amended: Filed April 27, 1965, effective May 7, 1965. Amended: Filed Dec. 7, 1966, effective Dec. 17, 1966. Amended: Filed Oct. 11, 1967, effective Oct. 21, 1967. Amended: Filed Oct. 19, 1967, effective Oct. 29, 1967. Amended: Filed Jan. 22, 1968, effective Feb. 2, 1968. Amended: Filed Aug. 24, 1968, effective Sept. 4, 1968. Amended: Filed April 16, 1970, effective April 26, 1970. Amended: Filed Feb. 16, 1971, effective Feb. 26, 1971. Amended: Filed Jan. 3, 1973, effective Jan. 13, 1973. Amended: Filed Feb. 6, 1975, effective Feb. 16, 1975. Amended: Filed March 9, 1977, effective June 11, 1977. Amended: Filed June 13, 1977, effective Oct. 1, 1977. Amended: Filed March 13, 1978, effective June 11, 1978. Amended: Filed Feb. 1, 1979, effective May 11, 1979. Emergency amendment filed July 26, 1979, effective Aug. 1, 1979, expired Oct. 10, 1979. Amended: Filed July 16, 1979, effective Oct. 11, 1979. Emergency amendment filed Aug. 11, 1981, effective Aug. 21, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 11, 1981, effective Nov. 12, 1981. Emergency amendment filed Dec. 21, 1981, effective Jan. 1, 1982, expired April 10, 1982. Emergency amendment filed Jan. 21, 1982, effective Feb. 1, 1982, expired April 10, 1982. Amended: Filed Dec. 21, 1981, effective April 11, 1982. Emergency amendment filed July 22, 1982, effective Aug. 1, 1982, expired Nov. 10, 1982. Amended: Filed July 22, 1982, effective Nov. 11, 1982. Emergency amendment filed Sept. 30, 1982, effective Oct. 10, 1982, expired Jan. 28, 1983. Amended: Filed Jan. 14, 1983, effective May 12, 1983. Amended: Filed July 13, 1983, effective Oct. 13, 1983. Emergency amendment filed Dec. 21, 1983, effective Jan. 1, 1984, expired March 30, 1984. Emergency amendment filed March 21, 1984, effective March 31, 1984, expired July 11, 1984. Amended: Filed March 21, 1984, effective July 12, 1984. Emergency amendment filed April 20, 1984, effective May 1, 1984, expired July 11, 1984. Amended: Filed June 13, 1984, effective Sept. 14, 1984. Amended: Filed Sept. 12, 1984, effective Jan. 12, 1985. Amended: Filed Jan. 15, 1985, effective April 11, 1985. Amended: Filed April 16, 1985, effective July 11, 1985. Amended: Filed Oct. 2, 1985, effective Jan. 1, 1986. Amended: Filed April 16, 1986, effective July 1, 1986. Amended: Filed Sept. 17, 1986, effective Dec. 1, 1986. Amended: Filed Nov. 14, 1986, effective Feb. 12, 1987. Emergency amendment filed Dec. 18, 1986, effective Jan. 1, 1987, expired Feb. 11, 1987. Amended: Filed Feb. 18, 1987, effective May 1, 1987. Amended: Filed April 17, 1987, effective July 1, 1987. Amended: Filed June 16, 1987, effective Sept. 1, 1987. Amended: Filed Aug. 18, 1987, effective Nov. 12, 1987. Amended: Filed Dec. 1, 1987, effective Feb. 11, 1988. Amended: Filed April 4, 1988, effective July 1, 1988. Amended: Filed July 15, 1988, effective Oct. 13, 1988. Amended: Filed Sept. 15, 1988, effective Dec. 11, 1988. Amended: Filed April 4, 1989, effective July 1, 1989. Amended: Filed June 6, 1989, effective Sept. 1, 1989. Amended: Filed June 30, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Amended: Filed Feb. 16, 1990, effective May 1, 1990. Amended: April 18, 1990, effective June 30, 1990. Amended: Filed Aug. 10, 1990, effective Dec. 31, 1990. Emergency amendment filed Dec. 21, 1990, effective Jan. 1, 1991, expired April 30, 1991. Emergency rescission and rule filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Emergency rescission filed April 2, 1991, effective April 12, 1991, expired Aug. 9, 1991. Emergency rule filed April 2, 1991, effective April 13, 1991, expired Aug. 10, 1991. Emergency amendment filed June 21, 1991, effective July 1, 1991, expired Aug. 10, 1991. Emergency rescission filed July 31, 1991, effective Aug. 11, 1991, expired Dec. 6, 1991. Rescinded: Filed March 21, 1991, effective Sept. 30, 1991. Emergency rule filed July 31, 1991, effective Aug. 11, 1991, expired Dec. 7, 1991. Readopted: Filed July 15, 1991, effective Jan. 13, 1992. Emergency amendment filed Sept. 23, 1991, effective Oct. 3, 1991, expired Dec. 7, 1991. Emergency rule filed Nov. 27, 1991, effective Dec. 8, 1991, expired April 5, 1992. Emergency amendment filed March 24, 1992, effective April 1, 1992, expired July 29, 1992. Emergency amendment filed June 16, 1992, effective July 1, 1992, expired Oct. 28, 1992. Amended: Filed March 24, 1992, effective Sept. 6, 1992. Emergency amendment filed Sept. 21, 1992, effective Oct. 1, 1992, expired Jan. 28, 1993. Emergency amendment filed Jan. 15, 1993, effective Jan. 29, 1993, expired May 28, 1993. Amended: Filed June 16, 1992, effective April 8, 1993. Emergency amendment filed March 19, 1993, effective April 1, 1993, expired July 29, 1993. Emergency amendment filed June 18, 1993, effective July 1, 1993, expired Oct. 28, 1993. Amended: Filed April 6, 1993, effective Dec. 9, 1993. Rescinded and readopted: Filed Oct. 15, 1993, effective June 6, 1994. Amended: Filed June 29, 2000, effective Dec. 30, 2000. Amended: Filed Aug. 28, 2018, effective April 30, 2019.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1981, 1986, 1988, 1990, 1992, 1993, 2004, 2005, 2007, 2011, 2013, 2014, 2015, 2016, 2018; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.031 List of Drugs for Which Prior Authorization Is Required and Drugs Excluded from Coverage Under the MO HealthNet Pharmacy Program

PURPOSE: This rule establishes a listing of drugs and categories of drugs for which prior authorization is required in order for them

to be reimbursable and for which reimbursement is not available under the MO HealthNet Pharmacy Program.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Exclusions — As used in section 208.152.1(12), RSMo, any "abortifacient drug or device" includes: mifepristone when used to induce an abortion; misoprostol when used to induce an abortion; manual vacuum aspirator (MVA) when used to induce an abortion; or any drug or device approved by the federal Food and Drug Administration (FDA) that the FDA has found on or after the effective date of section 208.152.1(12), RSMo, that is intended to cause the destruction of an unborn child as defined in section 188.015, RSMo.

(2) Exclusions — As specified in the Social Security Act, Section 1927(d)(1)(B), states may exclude or otherwise restrict coverage of certain covered outpatient drugs. Section 1927(d)(2) of the Social Security Act provides a listing of the categories of drugs that states may exclude. Drugs included on this list may be excluded from coverage entirely or restricted by diagnosis as determined by the state.

(3) As specified in Section 1927(d)(1) of the Social Security Act, states may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of Section 1927(d)(5) of the Social Security Act.

(4) List of drugs or categories of drugs for which prior authorization is required for certain specified indications, and those which are excluded from reimbursement through the MO HealthNet Pharmacy Program shall be made available through —

(A) MO HealthNet provider manuals, which are incorporated by reference and made a part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at http://manuals.momed.com/manuals/, September 27, 2018. This rule does not incorporate any subsequent amendments or additions;

(B) Provider Bulletins, which are incorporated by reference and made a part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at https://dss.mo.gov/mhd/providers/pages/bulletins.htm, September 27, 2018. This rule does not incorporate any subsequent amendments or additions; or

(C) Forms, which are incorporated by reference and made a part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at http://manuals.momed.com/manuals/presentation/forms.jsp, September 27, 2018. This rule does not incorporate any subsequent amendments or additions.

(5) The division reserves the right to effect changes in the list of drugs for which prior authorization is required and for which reimbursement is not available by amending this rule.

AUTHORITY: sections 1.205, 208.153, 208.201, and 660.017, RSMo 2016, and section 208.152, RSMo Supp. 2021. Original rule filed Dec. 13, 1991, effective Aug. 6, 1992. Amended: Filed May 15, 1992, effective Jan. 15, 1993. Amended: Filed March 1, 1996, effective Oct. 30, 1996. Amended: Filed May 27, 1999, effective Dec. 30, 1999. Emergency amendment filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Amended: Filed June 29, 2000, effective Feb. 28, 2001. Emergency amendment filed June 7, 2002, effective July 1, 2002, expired Dec. 27, 2002. Amended: Filed June 11, 2002, effective Jan. 30, 2003. Amended: Filed Jan. 16, 2007, effective July 30, 2007. Amended: Filed Sept. 16, 2013, effective March 30, 2014. Amended: Filed Sept. 27, 2018, effective May 30, 2019. Emergency amendment filed Oct. 21, 2021, effective Nov. 4, 2021, expired May 2, 2022. Amended: Filed Oct. 21, 2021, effective April 30, 2022.*

**Original authority: 1.205, RSMo 1986; 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1978, 1981, 1986, 1988, 1990, 1992, 1993, 2004, 2005, 2007, 2011, 2013, 2014, 2015, 2016, 2018, 2021; 208.153, RSMo 1967, amended 1967, 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.032 List of Excludable Drugs Excluded From Coverage Under the MO HealthNet Pharmacy Program
(Rescinded January 30, 2019)

AUTHORITY: sections 208.153 and 208.201, RSMo Supp. 2013. Original rule filed Dec. 13, 1991, effective Aug. 6, 1992. Amended: Filed June 30, 2000, effective Feb. 28, 2001. Emergency amendment filed June 7, 2002, effective July 1, 2002, expired Dec. 27, 2002. Amended: Filed June 11, 2002, effective Jan. 30, 2003. Amended: Filed Jan. 16, 2007, effective July 30, 2007. Amended: Filed Sept. 16, 2013, effective March 30, 2014. Rescinded: Filed June 8, 2018, effective Jan. 30, 2019.

13 CSR 70-20.033 Medicaid Program Coverage of Investigational Drugs Used in the Treatment of Acquired Immunodeficiency Syndrome (AIDS)
(Rescinded September 30, 2018)

AUTHORITY: sections 208.152, 208.153 and 208.201, RSMo 1994. Emergency rule filed Dec. 15, 1995, effective Jan. 1, 1996, expired June 28, 1996. Original rule filed Dec. 15, 1995, effective July 30, 1996. Rescinded: Filed March 2, 2018, effective Sept. 30, 2018.

13 CSR 70-20.034 List of Non-Excludable Drugs for Which Prior Authorization Is Required
(Rescinded May 30, 2019)

AUTHORITY: sections 208.152, 208.153, and 208.201, RSMo Supp. 2008. Emergency rule filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Original rule filed June 29, 2000, effective Feb. 28, 2001. Emergency amendment filed June 7, 2002, effective July 1, 2002, expired Dec. 27, 2002. Amended: Filed June 11, 2002, effective Jan. 30, 2003. Amended: Filed Jan. 16, 2007, effective July 30, 2007. Amended: Filed Aug. 17, 2009, effective Feb. 28, 2010. Rescinded: Filed Sept. 27, 2018, effective May 30, 2019.

13 CSR 70-20.040 Five Prescription Limit Per Month Per Recipient
(Rescinded January 30, 2019)

AUTHORITY: sections 208.153, RSMo Supp. 1991 and 208.201, RSMo Supp. 1987. This rule was previously filed as 13 CSR 40-81.012.

Emergency rule filed Oct. 21, 1981, effective Nov. 1, 1981, expired Feb. 10, 1982. Original rule filed Oct. 21, 1981, effective Feb. 11, 1982. Amended: Filed March 14, 1984, effective June 11, 1984. Amended: Filed June 12, 1984, effective Sept. 14, 1984. Amended: Filed Jan. 15, 1985, effective April 11, 1985. Amended: Filed April 16, 1985, effective July 11, 1985. Amended: Filed Oct. 2, 1985, effective Jan. 1, 1986. Amended: Filed April 16, 1986, effective July 1, 1986. Emergency amendment filed Dec. 18, 1986, effective Jan. 1, 1987, expired Feb. 11, 1987. Amended: Filed Sept. 17, 1986, effective Dec. 1, 1986. Amended: Filed Nov. 14, 1986, effective Feb. 12, 1987. Amended: Filed Feb. 18, 1987, effective May 1, 1987. Emergency amendment filed Dec. 18, 1986, effective Jan. 1, 1987, expired Feb. 11, 1987. Amended: Filed April 17, 1987, effective July 1, 1987. Amended: Filed June 16, 1987, effective Sept. 1, 1987. Amended: Filed Aug. 18, 1987, effective Nov. 12, 1987. Amended: Filed Dec. 1, 1987, effective Feb. 11, 1988. Amended: Filed April 15, 1988, effective July 1, 1988. Amended: Filed July 15, 1988, effective Oct. 13, 1988. Amended: Filed July 15, 1988, effective Oct. 13, 1988. Amended: Filed Sept. 15, 1988, effective Dec. 11, 1988. Amended: Filed April 4, 1989, effective July 1, 1989. Amended: Filed June 6, 1989, effective Sept. 1, 1989. Amended: Filed June 30, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Amended: Filed Aug. 13, 1990, effective Dec. 31, 1990. Emergency amendment filed Dec. 21, 1990, effective Jan. 1, 1991, expired April 30, 1991. Emergency amendment filed March 21, 1991, effective April 1, 1991, expired July 29, 1991. Amended: Filed March 13, 1991, effective Oct. 31, 1991. Rescinded: Filed June 8, 2018, effective Jan. 30, 2019.

13 CSR 70-20.042 Automatic Refill Program and Medication Synchronization Program

PURPOSE: This rule establishes the regulatory basis to prohibit automatic refill of prescriptions by providers for MO HealthNet participants. This rule also establishes policies for Medication Synchronization Programs in the MO HealthNet Pharmacy program.

(1) Definitions.

(A) Automatic Refill Program. Providers automatically refill prescribed medications, devices, or supplies at regular intervals without an explicit request from the participant, or the participant's responsible party, for each refill.

(B) Medication Synchronization Program. Designed to allow a participant to receive all maintenance medications on the same day. Before refilling any medications, the provider contacts the participant or the participant's responsible party to detect any new, discontinued, or changed medications. The provider only refills those medications requested by the participant or the participant's responsible party and coordinates pickup or delivery. Maintenance medications shall be as defined in 13 CSR 70-20.060.

(2) Automatic Refill Program.

(A) MO HealthNet does not allow automatic refills or automatic shipments of medications, devices, or supplies. MO HealthNet does not pay for any prescription without an explicit request from a participant or the participant's responsible party, such as a caregiver, for each refilling event. Participants and providers cannot waive the explicit refill request requirement and enroll in an automatic refill program.

(B) A nurse or other authorized agent of the facility may initiate a request for a refill for a participant residing in a skilled nursing facility, group home, or assisted living arrangement.

(C) Any prescription filled without a request from a participant or the participant's responsible party may be subject to recoupment. Any provider who pursues an automatic refill policy may be subject to audit, claim recovery, suspension, or termination of their provider agreement.

(3) Medication Synchronization Program.

(A) Documentation Required. The provider shall have written policies and procedures describing the Medication Synchronization Program which shall set forth, at a minimum, how the provider will comply with this section. The provider's written policies and procedures for the medication synchronization program shall be provided to the Department of Social Services upon request. Providers that do not provide the written policies and procedures within three (3) business days of the department's request may be subject to recoupment of any payments made to the provider by MO HealthNet for medications filled through the provider's medication synchronization program.

(B) Participant Enrollment. Before a participant enrolls, and annually thereafter, the provider shall provide a written or electronic notice summarizing the program to the participant or participant's responsible party. Such notice shall include, at a minimum, instructions about how to withdraw a medication from refill through the program or to disenroll entirely from the program. The participant or participant's responsible party must give the provider informed consent prior to enrolling in the Medication Synchronization Program, and annually thereafter.

(C) Products Allowed. Medication Synchronization Program shall only include non-controlled substance maintenance medications and are not allowed to include controlled substances (CII–CV), medications for acute treatment, or medications used on an as-needed basis.

(D) Medication Synchronization Program Contact. Providers with a medication synchronization program must contact the participant or the participant's responsible party before refilling any medication and confirm each medication to be refilled to ensure an accurate medication list. Medication Synchronization Program providers which generate or contribute to fraud, waste, or abuse will be subject to potential recoupment of claims and potential sanction of the provider.

(E) Record Keeping. The pharmacy shall keep a copy of the informed consent to enroll and annual informed consent to remain in the Medication Synchronization Program on file for five (5) years from the date of informed consent. Records of the medication synchronization program contact with the participant or the participant's responsible party for the purposes of refilling medications must be kept for audit purposes, including the date and time of contact for five (5) years from the date of dispensing.

(F) Penalties. Any prescriptions filled without a request from a participant or the participant's responsible party may be subject to recoupment. Any provider who pursues a policy that includes refilling prescriptions on a regular date or any type of cycle fill, without meeting the specifications herein, may be subject to audit, claim recovery, or possible suspension or termination of their provider agreement.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Original rule filed Dec. 15, 2022, effective July 30, 2023.*

**Original authority: 208.153, RSMo 1967, amended 1967, 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.045 Thirty-One-Day Supply Maximum Restriction on Pharmacy Services Reimbursed by the MO HealthNet Division

PURPOSE: This rule establishes a thirty-one- (31-) day supply maximum restriction per dispensing on pharmacy services reimbursed by the MO HealthNet Division on behalf of participants eligible for any of the fee-for-service programs.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) The maximum days' supply of medication that may be provided per dispensing on behalf of a participant eligible for any of the fee-for-service programs is thirty-one (31) days, except for those drugs and/or categories under the provisions of this rule. Medication may be dispensed in quantities less than a thirty-one- (31-) day supply, if so ordered by the prescriber, except as specified elsewhere in this rule.

(2) Drugs and/or categories of medications that are exempt from the thirty-one- (31-) day supply limitation and therefore may be dispensed in quantities exceeding a thirty-one- (31-) day supply are made available in the MO HealthNet Pharmacy Manual, section 13.6.D(1). The MO HealthNet Pharmacy Manual is incorporated by reference in this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website http://manuals.momed.com/manuals/, October 2, 2020. This rule does not incorporate any subsequent amendments or additions. The division reserves the right to effectuate changes in the list of drugs and/or categories of medications that are exempt from the thirty-one- (31-) day supply limitation by amending this rule.

(3) All spend down participants are exempt from the MO HealthNet thirty-one- (31-) day supply maximum restriction on pharmacy services.

(4) Exemptions from the thirty-one- (31-) day supply limitation may be given with prior authorization by the MO HealthNet Division to prevent a higher level of care.

(5) Drugs and/or categories of medications identified by 13 CSR 70-20.047 are exempt from the thirty-one- (31-) day supply limitation.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016, and section 208.152, RSMo Supp. 2020. Emergency rule filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Original rule filed June 29, 2000, effective Feb. 28, 2001. Amended: Filed Dec. 5, 2000, effective June 30, 2001. Amended: Filed April 18, 2018, effective Nov. 30, 2018. Amended: Filed Jan. 15, 2021, effective July 30, 2021.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1978, 1981, 1986, 1988, 1990, 1992, 1993, 2004, 2005, 2007, 2011, 2013, 2014, 2015, 2016, 2018; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.047 Ninety-Day Supply Requirement for Select Medications

PURPOSE: This rule establishes a ninety- (90-) day supply requirement per dispensing on select medications reimbursed by the MO HealthNet Division on behalf of participants eligible for any of the fee-for-service programs.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) MO HealthNet participating pharmacies shall dispense a ninety- (90-) day supply of select medications to a participant eligible for any of the fee-for-service programs. Drugs and/or categories of medications that are subject to this ninety- (90-) day supply requirement are identified in the *90-Day Supply Medication List*, which is incorporated by reference and made part of this rule as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at https://dss.mo.gov/mhd/cs/pharmacy/pages/frequpdat.htm, October 22, 2020. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016, and section 208.152, RSMo Supp. 2020. Original rule filed Jan. 15, 2021, effective July 30, 2021.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1978, 1981, 1986, 1988, 1990, 1992, 1993, 2004, 2005, 2007, 2011, 2013, 2014, 2015, 2016, 2018; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.050 Return of Drugs

PURPOSE: This rule establishes that pharmacies must give the MO HealthNet Division credit for any unused portion of the drug that is reusable in accordance with applicable federal or state law.

(1) The return and reuse of drugs must follow guidelines set by the State Board of Pharmacy in 20 CSR 2220-3.040, as amended.

(2) The pharmacy must give the MO HealthNet Division credit for all reusable items (any unused portion) not taken by the MO HealthNet participant. In instances in which charges have been submitted prior to the return of an item, the pharmacy shall file an adjustment prorated to the quantity of the drug used by the MO HealthNet participant.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Original rule filed Dec. 15, 2000, effective July 30, 2001. Amended: Filed Sept. 16, 2013, effective March 30, 2014. Amended: Filed April 18, 2018, effective Nov. 30, 2018. Amended: Filed May 28, 2021, effective Nov. 30, 2021.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.060 Professional Dispensing Fee

PURPOSE: The MO HealthNet Division establishes the amount of the fee reimbursable for the professional dispensing of each MO HealthNet covered prescription by a pharmacy provider.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Between April 1, 2017 and January 31, 2021, a professional dispensing fee shall be added to the MO HealthNet maximum allowable payment for MO HealthNet reimbursable prescriptions filled or refilled by a pharmacy provider as follows:

(A) Out-of-state pharmacy providers receive a professional dispensing fee of nine dollars fifty-five cents ($9.55);

(B) In-state pharmacy providers receive a professional dispensing fee of fourteen dollars thirty-seven cents ($14.37);

(C) In-state pharmacy providers receive a preferred generic product incentive fee of five dollars zero cents ($5.00); and

(D) The professional dispensing fees as provided in this rule shall not be included in the computation of the MO HealthNet maximum allowable drug payment for participant cost-sharing purposes.

(2) Effective February 1, 2021, a professional dispensing fee shall be added to the MO HealthNet maximum allowable payment for MO HealthNet reimbursable prescriptions filled or refilled by a pharmacy provider as follows:

(A) Out-of-state pharmacy providers receive a professional dispensing fee of eight dollars and eighty-five cents ($8.85);

(B) In-state pharmacy providers receive a professional dispensing fee of twelve dollars and twenty-two cents ($12.22), plus an adjustment to account for the costs of the Missouri Pharmacy Reimbursement Allowance attributable to Medicaid-reimbursed prescriptions;

(C) The professional dispensing fee as provided in this rule shall not be added to prescriptions reimbursed at the usual and customary charge submitted by the provider; and

(D) The professional dispensing fees as provided in this rule shall not be included in the computation of the MO HealthNet maximum allowable drug payment for participant cost-sharing purposes.

(3) Effective April 1, 2017, all pharmacy providers supplying prescribed MO HealthNet covered drugs to participants in long-term care facilities shall receive an additional fifty cent (50¢) dispensing fee per claim provided they —

(A) Dispense medication in a drug distribution system(s) which meets minimum standards of container packaging (at least class B as defined in United States Pharmacopeia XXI);

(B) Certify to the MO HealthNet Division, on a form, and in the manner prescribed by the division, that they —

1. Provide this dispensing service to their long-term care facility resident patients;

2. Provide emergency services twenty-four (24) hours a day with seven (7) days a week availability; and

3. Have the ability and willingness to assist in accessing medications through the MO HealthNet Exception Process; and

(C) Indicate, as prescribed by the MO HealthNet Division, on each claim that the prescription was provided in packaging qualifying for the dispensing fee add-on to a participant in a long-term care facility.

(4) A professional dispensing fee shall be added to maintenance medications no more frequently than once every twenty-five (25) days. "Maintenance medications" are defined as drugs that have a common indication for treatment of a chronic disease, and the therapeutic duration is expected to exceed one year. This is determined by a First DataBank drug code maintenance indicator of "1."

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Original rule filed Dec. 15, 1987, effective March 11, 1988. Amended: Filed Sept. 26, 2013, effective March 30, 2014. Emergency amendment filed Jan. 13, 2021, effective Feb. 1, 2021, expired July 30, 2021. Amended: Filed Jan. 13, 2021, effective July 30, 2021.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.070 Drug Reimbursement Methodology

PURPOSE: This rule establishes the basis and the method for pricing all drug claims in Missouri under the Title XIX Medicaid program. The purchase of a computer-generated tape, with weekly updates, will make it possible to utilize the computer for review purposes, which greatly increases the speed with which claims can be paid.

(1) The MO HealthNet Division will obtain, by contract with a reputable medical publishing company, a weekly computer-generated tape which will provide the information needed to price all fee-for-service Medicaid drug claims. The tape will contain National Drug Code (NDC), drug name, drug strength, dosage form, package size, the prices set by direct-selling manufacturers (direct prices), Wholesaler Acquisition Cost (WAC), federal Health and Human Services upper limits for specified multiple source drugs (FUL), and National Average Drug Acquisition Cost (NADAC). A multiple source drug is defined as a drug marketed or sold by two (2) or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two (2) or more different proprietary names or both under a proprietary name and without that name.

(2) The MO HealthNet Division will add the Missouri Maximum Allowable Cost (MMAC) limits, for multiple source drugs as defined, to the data shown on the tape described in section (1) of this rule.

(3) Effective December 16, 2018, reimbursement for covered drugs will be determined by applying the following hierarchy method:

(A) National Average Drug Acquisition Cost (NADAC); if there is no NADAC;

(B) Missouri Maximum Allowed Cost (MAC); if no NADAC or MAC;

(C) Wholesale Acquisition Cost (WAC); or

(D) The usual and customary (U&C) charge submitted by the provider if it is lower than the chosen price (NADAC, MAC, or WAC).

1. U&C is defined as the provider's charge to the general

public that reflects all discounts or programs such as, but not limited to, discount programs, membership programs, price matching programs, or any other program offered by the provider to initiate a reduced price for product costs available to the general public, a special population, or an inclusive category of customers, on the date of service.

2. General public is defined as those patients that pay for their prescriptions and the prescription is not processed by a third-party which includes both governmental and non-governmental payers.

(4) Reimbursement for covered drugs for 340B providers as defined in 42 U.S.C. 256b(a)(4) and 42 U.S.C. 1396r-8(a)(5)(B) who carve-in for Medicaid will be calculated according to 13 CSR 70-20.075.

(5) The professional dispensing fee will be calculated according to 13 CSR 70-20.060.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016, and section 208.152, RSMo Supp. 2021. This rule was previously filed as 13 CSR 40-81.150. Original rule filed April 23, 1979, effective Aug. 11, 1979. Emergency amendment filed Sept. 9, 1981, effective Oct. 1, 1981, expired Dec. 10, 1981. Amended: Filed Sept. 9, 1981, effective Dec. 11, 1981. Emergency amendment filed Oct. 19, 1987, effective Oct. 29, 1987, expired Feb. 25, 1988. Amended: Filed Dec. 1, 1987, effective Feb. 11, 1988. Emergency amendment filed March 29, 1988, effective April 8, 1988, expired Aug. 5, 1988. Amended: Filed May 3, 1988, effective July 28, 1988. Emergency amendment filed Dec. 21, 1990, effective March 17, 1991, expired April 30, 1991. Emergency amendment filed March 6, 1991, effective March 17, 1991, expired July 14, 1991. Emergency amendment filed Sept. 4, 1991, effective Sept. 17, 1991, expired Jan. 14, 1992. Amended: Filed Sept. 4, 1991, effective Jan. 13, 1992. Amended: Filed Dec. 5, 2000, effective June 30, 2001. Amended: Filed July 19, 2018, effective March 30, 2019. Emergency amendment filed April 26, 2021, effective July 1, 2021, expired Feb. 24, 2022. Amended: Filed April 26, 2021, effective Nov. 30, 2021.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1981, 1986, 1988, 1990, 1992, 1993, 2004, 2005, 2007, 2011, 2013, 2014, 2015, 2015, 2018, 2021; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.071 Multiple Source Drugs for Which There Exists a Federal Upper Limit on Reimbursement
(Rescinded September 30, 2018)

AUTHORITY: sections 208.153 and 208.201, RSMo Supp. 2013. Emergency rule filed Oct. 19, 1987, effective Oct. 29, 1987, expired Feb. 25, 1988. Emergency amendment filed Oct. 29, 1987, effective Nov. 8, 1987, expired March 6, 1988. Original rule filed Dec. 1, 1987, effective Feb. 11, 1988. Emergency amendment filed June 21, 1988, effective July 1, 1988, expired Oct. 28, 1988. Amended: Filed Aug. 16, 1988, effective Oct. 29, 1988. Emergency amendment filed May 12, 1989, effective June 1, 1989, expired Sept. 23, 1989. Amended: Filed May 12, 1989, effective Aug. 11, 1989. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Amended: Filed April 18, 1990, effective June 30, 1990. Emergency amendment filed Aug. 20, 1990, effective Sept. 1, 1990, expired Dec. 30, 1990. Amended: Filed Sept. 5, 1990, effective Feb. 14, 1991. Emergency amendment filed Dec. 20, 1990, effective Dec. 31, 1990, expired April 29, 1991. Emergency amendment filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Amended: Filed April 2, 1991, effective Oct. 31, 1991. Emergency amendment filed Dec. 4, 1992, effective Dec. 15, 1992, expired April 13, 1993. Emergency rescission and emergency rule filed April 2, 1993, effective April 13, 1993, expired Aug. 10, 1993. Amended: Filed Aug. 27, 1993, effective May 9, 1994. Amended: Filed Sept. 26, 2013, effective March 30, 2014. Rescinded: Filed March 2, 2018, effective Sept. 30, 2018.

13 CSR 70-20.075 340B Drug Pricing Program

PURPOSE: This rule establishes the payment methodology for 340B-covered entities as defined in section 1927(a)(5)(B) of the Social Security Act that choose to carve-in Medicaid.

(1) 340B-covered entities that choose to carve-in Medicaid must provide the Health Resources and Services Administration (HRSA) with their National Provider Identification (NPI) and their MO HealthNet Division (MHD) provider number for each site that carves in for inclusion in the HRSA Medicaid Exclusion File. The MHD requires the MO HealthNet provider number to be included on the Medicaid Exclusion File to identify providers that carve-in Medicaid and to prevent duplicate discounts.

(2) 340B-covered entities are required to identify 340B-purchased drugs at the claims level using the following codes:

(A) Point-of-sale pharmacy claims: Submission Clarification Code (SCC) 20; and

(B) Medical and outpatient claims: Modifier JG or TB.

(3) Failure to include the appropriate submission clarification code or modifier on a 340B-purchased drug will result in the MHD collecting rebate on the claim and may subject the covered entity to audit penalties. The MHD will deny claims from providers who submit an SCC of 20 or 340B modifier but have not notified HRSA of carve-in status.

(4) Effective July 1, 2021, reimbursement for 340B-identified covered drugs for 340B providers as defined by 42 U.S.C. 256b(a)(4) and 42 U.S.C. 1396r-8(a)(5)(B) who carve-in for Medicaid will be determined by applying the following method:

(A) 340B-purchased drugs dispensed by pharmacy providers will be reimbursed at their actual acquisition cost, up to the 340B Maximum Allowable Cost (MAC) (calculated ceiling price) plus a professional dispensing fee. Covered entities are required to bill no more than their actual acquisition cost plus the professional dispensing fee.

1. The 340B MAC (calculated ceiling price) is defined as the Average Manufacturer Price (AMP) minus Unit Rebate Agreement (URA).

2. Actual acquisition cost is defined as the invoice cost for the NDC per billing unit. This does not include timely pay discounts or discounts paid as a rebate on a separate invoice for volume-based purchases; and

(B) Physician-administered drugs purchased through the 340B program will be reimbursed the lesser of the Physician-Administered 340B MAC or the actual acquisition cost submitted by the provider. A professional dispensing fee is not applied to physician-administered drugs.

1. The Physician-Administered 340B MAC is calculated by adding six percent (6%), up to six hundred dollars ($600), to the calculated ceiling price.

(5) 340B contract pharmacies are not covered under this policy and must carve-out Medicaid from their 340B operation unless

MHD approves an exception.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Emergency rule filed April 26, 2021, effective July 1, 2021, expired Feb. 24, 2022. Original rule filed April 26, 2021, effective Nov. 30, 2021.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.080 Labeling of Medicaid Prescriptions
(Rescinded December 9, 1993)

AUTHORITY: sections 207.020, RSMo 1986 and 208.153, RSMo Supp. 1991. This rule was previously filed as 13 CSR 40-81.030. Original rule file Oct. 24, 1974, effective Nov. 3, 1974. Rescinded: Filed April 6, 1993, effective Dec. 9, 1993.

13 CSR 70-20.100 Missouri Nonsteroidal Anti-Inflammatory Drug List
(Rescinded September 30, 1991)

AUTHORITY: sections 208.153 and 208.201, RSMo Supp. 1989. This rule was previously filed as 13 CSR 40-81.013. Original rule filed Feb. 18, 1987, effective June 1, 1987. Amended: Filed April 4, 1989, effective July 1, 1989. Amended: Filed Aug. 13, 1990, effective Dec. 31, 1990. Emergency rescission filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Rescinded: Filed March 21, 1991, effective Sept. 30, 1991.

13 CSR 70-20.110 Medicaid Program Coverage of Approved Drugs for Treatment of Acquired Immunodeficiency Syndrome (AIDS)
(Rescinded September 30, 1991)

AUTHORITY: sections 208.153, RSMo 1986 and 208.201, RSMo Supp. 1988. Emergency rule filed July 9, 1987, effective July 19, 1987, expired Nov. 15, 1987. Original rule filed July 31, 1987, effective Nov. 12, 1987. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Emergency rescission filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Rescinded: Filed March 21, 1991, effective Sept. 30, 1991.

13 CSR 70-20.120 Medicaid Program Coverage of Anti-Ulcer Preparations
(Rescinded June 29, 1989)

AUTHORITY: sections 208.153, RSMo 1986 and 208.201, RSMo Supp. 1987. Original rule filed Oct. 18, 1988, effective Jan. 1, 1989. Amended: Filed March 16, 1989. Emergency rescission filed April 7, 1989, effective April 20, 1989, expired Aug. 17, 1989. Rescinded: Filed April 7, 1989, effective June 29, 1989.

13 CSR 70-20.200 Drug Prior Authorization Process

PURPOSE: This rule establishes the division process by which drugs may be restricted under Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990) and are determined to be appropriate for inclusion as a regular benefit of the MO HealthNet program or through prior authorization.

(1) The following definitions shall be used in the interpretation and enforcement of this rule:

(A) "Clinical editing" shall be defined as that process which screens the use of specific medications on the basis of clinical appropriateness by requiring evidence of appropriate indications for use and to achieve a cost savings, may require the initial use of less expensive agents;

(B) "Fiscal editing" shall be defined as a process that screens the use of specific medications to reimburse based on the least expensive dosage forms in order to achieve a cost savings;

(C) "Open access" shall be defined as the availability of a product without being subjected to prior authorization, clinical edits, or step therapy but shall not preclude fiscal and utilization edits;

(D) "Preferred Drug List" shall be defined as a list of medications within a functional therapeutic class that are available via open access on the basis of supplemental rebate status and consideration of available evidence-based clinical review findings;

(E) "Step therapy" shall be defined as a process that specifies the sequence in which different prescription drugs are to be reimbursed; and

(F) "Utilization edits" are defined as prospective screening edits used to review the appropriate use of medication and may be advisory or preemptory.

(2) All persons eligible for medical assistance benefits shall have access to all pharmaceutical products for which there is federal financial participation except those drugs that may be restricted under Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990). The MO HealthNet Division shall review those drugs that may be restricted and recommend to the Drug Utilization Review (DUR) Board those appropriate for inclusion as a regular benefit of the MO HealthNet program or through prior authorization.

(3) The department or the division may require prior authorization of pharmaceutical products. Any such restriction shall be based on medical and clinical criteria, and Missouri-specific data. The MO HealthNet Division shall develop this medical and clinical criteria based on predetermined standards consistent with the following:

(A) The American Hospital Formulary Service Drug Information;

(B) The *United States Pharmacopoeia* Drug Information; and

(C) Peer-reviewed medical literature.

(4) The MO HealthNet Division shall review medications used to treat rare medical conditions with the Rare Disease Advisory Council. The MO HealthNet Division shall develop medical and clinical criteria and make recommendations to the Rare Disease Advisory Council. Proposals approved by the Rare Disease Advisory Council shall be presented to the DUR Board.

(5) The DUR Board shall hold a public hearing at least once every ninety (90) days during which the MO HealthNet Division shall make recommendations to the board and prior to any final decision by the division to require prior authorization for that pharmaceutical product, class, or category.

(6) The tentative meeting agenda of the DUR Board with the therapeutic classes to be discussed shall be posted on the MO HealthNet Division website (www.dss.mo.gov/mhd) approximately fourteen (14) days prior but no less than seven (7) days prior to the meeting.

(A) The specific therapeutic class or classes to be considered

at the next regularly scheduled DUR Board meeting shall be placed on the current agenda or posted on the website approximately thirty (30) days prior to the scheduled meeting.

(B) Any interested party shall be granted the opportunity for clinically relevant public comment for up to five (5) minutes per medication under review by the DUR Board. The responsibility of scheduling the presentation shall rest with the interested party. Interested parties representing a manufacturer shall be granted five (5) minutes in the aggregate per medication under review by the DUR Board.

(C) Following the consideration of all presented information, the DUR Board may accept or alter the recommendations from the MO HealthNet Division. The board shall make their final recommendation to the MO HealthNet Division by a majority vote of the members of the committee present thereto in a recorded roll call vote.

(D) The specific therapeutic class or classes recommended for restriction by means of step therapy, clinical edit, fiscal edit, or preferred drug list shall be available on the division website at www.dss.mo.gov/mhd approximately fifteen (15) calendar days after the meeting.

(7) After all recommendations have been reviewed and accepted, the MO HealthNet Division staff shall coordinate the implementation of the recommendations. All pertinent information relating to edit implementation schedule and edit criteria shall be made available to the public by reasonable means, including, but not limited to, posting on the division website in a timely fashion following the DUR board meeting. Changes to the MO HealthNet pharmacy benefit will be posted on a timely basis on the division website. In addition, information on covered medications shall be made available to the public. As determined by the division, patients stabilized on certain restricted medications may be allowed to access such medication through the MO HealthNet program for as long as the MO HealthNet program determines that it is fiscally prudent and clinically supported.

(8) On an annual basis, the DUR Board shall review all criteria in place, including prior authorization, step therapy, clinical edits, fiscal edits, and the preferred drug list. Annual reviews will be staggered and scheduled to occur at the scheduled meeting closest to completion of a full calendar year after approval of the criteria. If additional clinical or fiscal information is available since the original consideration, interested parties shall have the opportunity to address the board and request reconsideration of prior authorization, step therapy, clinical edits, fiscal edits, and preferred drug list criteria as part of the annual review. All such presentations shall be clinically relevant and limited to a maximum of five (5) minutes. The responsibility of scheduling the presentation shall rest with the interested party.

(9) The division shall not otherwise restrict the prescribing and dispensing of covered outpatient prescription drugs (other than Drug Efficacy Study Implementation (DESI) drugs as designated by federal law) pursuant to this rule without consulting the DUR Board. The division may limit the number of prescriptions allowed for each medical assistance participant.

(10) As used in the rule, DESI drugs are drugs described in section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (within the meaning of section 310.6(b)(1) of Title 21 of the *Code of Federal Regulations*).

(11) When implementing the provisions of section (3) of this rule, Missouri-specific data shall include the consideration of use and cost data, pharmacoeconomic information and prudent utilization of state funds, and shall include medical and clinical criteria.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Original rule filed Feb. 3, 1992, effective Aug. 6, 1992. Emergency amendment filed May 22, 2002, effective June 1, 2002, expired Nov. 27, 2002. Amended: Filed June 3, 2002, effective Nov. 30, 2002. Amended: Filed Dec. 14, 2004, effective June 30, 2005. Amended: Filed Sept. 26, 2013, effective March 30, 2014. Amended: Filed Sept. 16, 2020, effective March 30, 2021.*

**Original authority: 208.153, RSMo 1967, amended, 1967, 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.250 Prior Authorization of New Drug Entities or New Drug Dosage Form

PURPOSE: This rule outlines the process by which new drugs or new drug dosage forms of existing drugs may be subject to prior authorization prior to payment by Missouri's medical assistance program.

(1) New drug entities, and new drug product dosage forms of existing drug entities, that have been approved by the Food and Drug Administration and are available on the market, shall comply with prior authorization requirements imposed by the division, in compliance with federal law.

(2) Prior authorization restrictions shall continue on new drug entities and new drug product dosage forms of existing drugs until reviewed by the division and the division eliminates the restriction or makes a final determination to require restriction. The division shall consider known cost and use data, medical and clinical criteria, and prudent utilization of state funds in the review. Interested parties may present clinical data to the division.

(3) The review referenced in section (2) shall occur within thirty (30) business days after the division receives notice through pricing updates of the availability of the drug entity on the market. Upon completion of the review, the division shall make the drug available for use by all MO HealthNet participants or refer the new drug or new drug dosage form to the MO HealthNet Drug Utilization Review (DUR) Board with a recommendation for continued prior authorization. Staff recommendations regarding continued prior authorization of a new drug or new drug dosage form shall be made in writing to the DUR Board. A copy shall be available to the public prior to the DUR Board meeting in which the continued prior authorization is to be discussed.

(4) The DUR Board shall consider any recommendations related to continued prior authorization of a new drug or new drug dosage form at the next scheduled DUR Board meeting. The division and the DUR Board may actively seek comments about the proposed restrictions. The DUR Board shall include five (5) minutes for any interested parties who have notified the division in advance of the scheduled meeting to comment about such proposed restrictions.

(5) If the DUR Board finds that use and cost data, pharmacoeconomic information, along with medical and

clinical implications of restriction, are documented and restriction is warranted, the DUR Board shall hold a public hearing regarding the continued restriction and make a recommendation to the division. Such recommendation shall be provided to the division, in writing, prior to the division making a final determination. The division shall provide notice of the final determination through the Department of Social Services, MO HealthNet Division website at dss.state.mo.gov/mhd, provider bulletins, and updates to the provider manual.

(6) If, after the hearing referenced in section (5) above, prior authorization of the new drug or new drug dosage form is required, the prior authorization requirement shall be reviewed at least once every twelve (12) months by the DUR Board.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Emergency rule filed May 22, 2002, effective June 1, 2002, expired Nov. 27, 2002. Original rule filed June 3, 2002, effective Nov. 30, 2002. Amended: Filed Sept. 16, 2013, effective March 30, 2014. Amended: Filed Jan. 20, 2021, effective July 30, 2021.*

**Original authority: 208.153, RSMo 1967, amended 1967, 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.300 Retrospective Drug Use Review Process

PURPOSE: This rule establishes the division process by which the Drug Utilization Review Board will be established as required by Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990) and by section 208.175, RSMo.

(1) Drug Utilization Review (DUR) Board. This rule establishes a MO HealthNet DUR Board in the Department of Social Services, MO HealthNet Division. The board shall be composed as specified in section 208.175, RSMo.

(2) A chairperson shall be elected by the board members.

(3) The DUR Board shall meet at least once every ninety (90) days. A quorum of two-thirds (2/3) of the total members, including no fewer than three (3) physicians or three (3) pharmacists, is required for the board to act in its official capacity.

(4) Members shall serve four- (4-) year terms, except the terms of the original members, two (2) shall be appointed for a term of two (2) years, three (3) shall be appointed for a term of three (3) years, and three (3) shall be appointed for a term of four (4) years. Members may be reappointed, provided that minimum qualifications for membership continue to be met. Nominations shall be referred for final appointment by the governor subject to advice and consent of the senate. As vacancies occur, the DUR Board shall solicit and select a slate of nominees.

(5) The members of the DUR Board shall receive no compensation for their services other than reasonable expenses actually incurred in the performance of their official duties.

(6) The DUR Board shall hold a public hearing during which the MO HealthNet Division shall make recommendations to the board. The hearing shall be prior to any final decision by the division to require prior authorization for that pharmaceutical product, class, or category.

(7) The tentative meeting agenda of the DUR Board with the therapeutic classes to be discussed shall be posted on the MO HealthNet Division website (www.dss.mo.gov/mhd) approximately fourteen (14) days prior but no less than seven (7) days prior to the meeting.

(A) The specific therapeutic class or classes to be considered at the next regularly scheduled DUR Board meeting shall be placed on the current agenda or posted on the website approximately thirty (30) days prior to the scheduled meeting.

(B) Any interested party shall be granted the opportunity for clinically relevant public comment for up to five (5) minutes per medication under review by the DUR Board. The responsibility of scheduling the presentation shall rest with the interested party. Interested parties representing a manufacturer shall be granted five (5) minutes in the aggregate per medication under review by the DUR Board.

(C) Following the consideration of all presented information, the DUR Board may accept or alter the recommendations from the MO HealthNet Division. The board shall make their final recommendation to the MO HealthNet Division by a majority vote of the members of the committee present thereto in a recorded roll call vote.

(D) The specific therapeutic class or classes recommended for restriction by means of step therapy, clinical edit, fiscal edit, or preferred drug list shall be available on the division website at www.dss.mo.gov/mhd approximately fifteen (15) calendar days after the meeting.

(8) Any changes recommended by the DUR Board shall be made available via the approved minutes of the DUR Board meeting in a timely fashion, at least thirty (30) days prior to the implementation of the recommendations.

(9) The DUR Board shall provide, either directly or through contracts between the MO HealthNet Division and accredited health care schools, state medical societies, or state pharmacist associations or societies or other appropriate organizations, for educational outreach programs as required by P.L. 101-508, Section 4401, to educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. This outreach shall include an educational newsletter to MO HealthNet providers including appropriate drug use guidelines and MO HealthNet utilization statistics. The board activities shall include:

(A) Establishment and implementation of medical standards and criteria for the prospective and retrospective DUR program;

(B) Development, selection, application, and assessment of educational interventions for physicians, pharmacists, and participants that improve care; and

(C) Administration of the Drug Prior Authorization Process as outlined in 13 CSR 70-20.200.

(10) As specified by P.L. 101-508, Section 4401, the DUR Board shall monitor drug use, and prescribing and dispensing practices in the MO HealthNet program. This monitoring shall include reviewing and refining therapeutic criteria modules used in both retrospective and prospective DUR, as well as overseeing retrospective DUR intervention methods used.

(11) The DUR Board shall advise the Department of Social Services regarding all activities associated with the DUR process, including identifying types of intervention methods to be initiated by the review committees, ranging from letters to physicians and pharmacists, face-to-face education, and educational symposiums for targeted providers. The board

shall provide educational support and guidance as needed by the review committees. The review committees, in turn, shall report intervention results and make recommendations based on these results to the board.

(12) Patterns of inappropriate or aberrant prescribing or dispensing shall be identified and referred to the board in order for targeted education to be formulated.

(13) Agency Responsibility Regarding Confidentiality of Information. All information concerning applicants and MO HealthNet participants shall be confidential and any disclosure of this information shall be restricted to purposes directly related to the administration of the medical assistance program. Purposes directly related to administration of the medical assistance program include:

(A) Establishing eligibility;

(B) Determining the amount of medical assistance;

(C) Providing services for recipients; and

(D) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program.

(14) Provider Responsibility Regarding Confidentiality of Information. All information concerning applicants and participants of medical services shall be confidential. Any disclosure of this information shall be restricted to purposes directly related to the treatment of the patient and promotion of improved quality of care. The confidential information includes:

(A) Names and addresses;

(B) Social Security number;

(C) Medical services provided;

(D) Social and economic conditions or circumstances;

(E) Medical data, including diagnosis and past history of disease or disability;

(F) Any information received for verifying income eligibility; and

(G) Any information received in connection with the identification of legally liable third-party resources.

AUTHORITY: sections 208.153, 208.175, 208.201, and 660.017, RSMo 2016. Original rule filed Dec. 14, 1992, effective June 7, 1993. Amended: Filed Sept. 16, 2013, effective March 30, 2014. Amended: Filed Sept. 16, 2020, effective March 30, 2021.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.175, RSMo 1992, amended 1993, 2011, 2014; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.310 Prospective Drug Use Review Process and Patient Counseling

PURPOSE: This rule establishes provisions for prospective drug use review and patient counseling for MO HealthNet beneficiaries, as required by Section 4401 or Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990) and by section 208.176, RSMo.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Prospective Drug Use Review (DUR). This rule establishes a MO HealthNet prospective drug use review process within the Department of Social Services, MO HealthNet Division, as specified in section 208.176, RSMo.

(2) Electronic Point-of-Sale Review. The MO HealthNet Division shall provide for electronic point-of-sale review before each prescription is dispensed to a MO HealthNet participant or MO HealthNet participant's caregiver on the date of service. The Missouri Drug Use Review Board will review and approve clinical modules, as outlined in 42 CFR 456.705, Prospective Drug Review as published on October 1, 2018 by the Office of the Federal Register National Archives and Records Administration, US Government Publishing Office US Superintendent of Documents, Washington, DC 20402 and is incorporated by reference and made a part of this rule, as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Ct, Jefferson City, MO 65109, at its website at https://dssruletracker.mo.gov/dss-proposed-rules/welcome.action. This rule does not incorporate any subsequent amendments or additions. The MO HealthNet Division will provide electronic point-of-sale screening for potential drug therapy problems using the approved clinical modules on the date of service.

(3) Electronic Point-of-Sale Review Available for MO HealthNet Beneficiaries. The following reviews will be provided by the pharmacy point of service system:

(A) Drug Disease Contraindications.

1. Drug (actual) disease precaution.
2. Inferred Drug Disease precaution;

(B) Drug to Drug Interactions;

(C) Side Effects.

1. Additive toxicity side effects.
2. Medical condition/additive side effect.
3. Side effect.
4. Drug indicated for side effect of previously prescribed drug;

(D) Dose Range Checking.

1. High dose alert.
2. Low dose alert;

(E) Minimum/Maximum Daily Dose.

1. High dose alert.
2. Low dose alert;

(F) Duplicate Therapy Checking.

1. Therapeutic duplication.
2. Ingredient duplication; and

(G) Duration of Therapy (H2).

1. Excessive duration alert.

(4) MO HealthNet Patient Counseling. As part of the prospective DUR program, participating pharmacies shall perform patient counseling according to the standards established by the Board of Pharmacy under 20 CSR 2220-2.190. 20 CSR 2220-2.190 is published by the Missouri Secretary of State, at https://www.sos.mo.gov/cmsimages/adrules/csr/current/20csr/20c2220-2.pdf, on February 28, 2017. A copy of 20 CSR 2220-2.190 is incorporated by reference and made a part of this rule, as published by the Department of Social Services, MO HealthNet Division, 615 Howerton Ct., Jefferson City, MO 65109, at its website at https://dssruletracker.mo.gov/dss-proposed-rules/welcome.action. This rule does not incorporate

any subsequent amendments or additions.

(5) MO HealthNet Patient Profiles. The term "reasonable effort" means that each time a MO HealthNet patient or caregiver presents a prescription, the pharmacist or pharmacist's designee should request profile information verbally or in writing. For example, if the patient presents the prescription in person, the request should be made verbally, and if the prescription is received by mail, the request should be made in writing. This does not imply that the service should be denied solely on the basis of the patient's refusal to supply this information. Pharmacies must make a reasonable effort to obtain records and maintain patient profiles containing, at a minimum:

(A) The name, address, telephone number, date of birth (or age), and gender of the patient;

(B) Individual medical history, if significant, including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(C) Pharmacist's comments relevant to the individual's drug therapy.

(6) Documentation of Offer to Counsel. The pharmacist shall document for each MO HealthNet patient's prescription in a uniform fashion, whether the offer to counsel was accepted or refused by the patient or the patient's agent.

(7) Agency Responsibility Regarding Confidentiality of Information. All information concerning applicants and participants of medical services shall be kept confidential by the MO HealthNet Division, and any disclosure of this information shall be restricted to purposes directly related to the administration of the medical assistance program. Purposes directly related to administration of the medical assistance program include:

(A) Establishing eligibility;

(B) Determining the amount of medical assistance;

(C) Providing services for participants; and

(D) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program.

(8) Provider Responsibility Regarding Confidentiality of MO HealthNet Beneficiary Information. All information concerning applicants and participants of medical services shall be confidential. Any disclosure of this information by the pharmacy provider shall be restricted to purposes directly related to the treatment of the patient and promotion of improved quality of care, or conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program. The confidential information includes:

(A) Names and addresses;

(B) Social Security number;

(C) Medical services provided;

(D) Social and economic conditions or circumstances;

(E) Medical data, including diagnosis and past history of disease or disability;

(F) Any information received for verifying income eligibility; and

(G) Any information received in connection with the identification of legally liable third party resources.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Original rule filed June 3, 1993, effective Dec. 9, 1993. Amended: Filed Sept. 16, 2013, effective March 30, 2014. Amended: Filed Nov. 27, 2019, effective June 30, 2020.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.320 Pharmacy Reimbursement Allowance

PURPOSE: This rule establishes a Pharmacy Federal Reimbursement Allowance and the methodologies to determine the formula for the amount of allowance each pharmacy is required to pay for the privilege of providing outpatient prescription drugs.

(1) Pharmacy Reimbursement Allowance (PRA). PRA shall be assessed as described in this section.

(A) Definitions.

1. Department – Department of Social Services.

2. Director – Director of Department of Social Services.

3. Division – MO HealthNet Division.

4. Gross retail prescription receipts – For ease of administration for the department as well as the industry, this shall be an annual amount. The basis of tax in any fiscal year will be the gross prescription sales of the last calendar year prior to the previous fiscal year.

(B) Each pharmacy engaging in the business of providing outpatient prescription drugs in Missouri to the general public shall pay a PRA.

1. The PRA owed for existing pharmacies shall be calculated by multiplying the pharmacy's total gross retail prescription receipts by the tax rate determined by the department. Subject to the limitations established in section 338.520, RSMo, such said tax rate shall be uniform and shall not exceed five percent (5%).

2. The PRA shall be divided by and collected over the number of months for which the PRA is effective.

3. The initial PRA owed by a newly licensed pharmacy shall be calculated by estimating the total prescription sales and multiplying the estimate by the rate determined by the department, as described in paragraph (1)(B)1.

4. If a pharmacy ceases to provide outpatient prescription drugs to the general public, the pharmacy is not required to pay the PRA during the time it did not provide outpatient prescription drugs.

5. If the pharmacy reopens, it shall resume paying the PRA. It shall owe the same PRA as it did prior to closing, if the PRA has not changed per paragraph (1)(B)1.

(C) Each pharmacy shall submit an affidavit to the department with the following information:

1. Pharmacy name;

2. Contact;

3. Telephone number;

4. Address;

5. Federal tax ID number;

6. MO HealthNet pharmacy number (if applicable);

7. Pharmacy sales (total);

8. MO HealthNet pharmacy sales;

9. Number of paid MO HealthNet prescriptions; and

10. Gross receipts attributable to prescription drugs that are delivered directly to the patient via common carrier, by mail, or a courier service.

(D) The department shall prepare a confirmation schedule of the information provided by each pharmacy and the amount of PRA that is due from the pharmacy.

(E) Each pharmacy shall review the information prepared by the department and the amount of PRA calculated by the department to verify that the information is correct.

1. If the information supplied by the department is incorrect, the facility, within thirty (30) calendar days of receiving the confirmation schedule must notify the division and explain the correction.

2. If the division does not receive corrected information within thirty (30) calendar days, it will be assumed to be correct, unless the pharmacy files a protest in accordance with subsection (2)(D) of this regulation.

(2) Payment of the PRA.

(A) Offset.

1. Each pharmacy may request that its PRA offset against any MO HealthNet payment due to that pharmacy.

A. A statement authorizing the offset must be on file with the division before any offset may be made relative to the PRA by the pharmacy.

B. Assessments shall be allocated and deducted over the applicable service period.

C. Any balance due after the offset shall be remitted to the director of the Department of Revenue and be deposited in the state treasury to the credit of the Pharmacy Reimbursement Allowance Fund.

D. If the remittance is not received before the next MO HealthNet payment cycle, the division shall offset the balance due from that check.

(B) Check.

1. If no offset has been authorized by the pharmacy, the division will begin collecting the pharmacy reimbursement allowance on the first day of each month for the preceding months.

2. The PRA shall be remitted by the pharmacy to the department. The remittance shall be made payable to the director of the Department of Revenue and be deposited in the state treasury to the credit of the Pharmacy Reimbursement Allowance Fund.

(C) Failure to comply with this request for information or failure to pay the PRA.

1. If a pharmacy fails to comply with a request for information from the MO HealthNet Division or fails to pay its PRA within thirty (30) days of notice, the PRA shall be delinquent.

2. For any delinquent PRA, the department may —

A. Proceed to enforce the state's lien of the property of the pharmacy;

B. Cancel or refuse to issue, extend, or reinstate the MO HealthNet provider agreement; or

C. Seek denial, suspension, or revocation of license granted under Chapter 338, RSMo.

3. The new owner, as a result of a change in ownership, shall have his/her PRA paid by the same method the previous owner elected.

(D) Each pharmacy, upon receiving written notice of the final determination of its PRA, may file a protest with the director of the department setting forth the grounds on which the protest is based, within thirty (30) days from the date of receipt of written notice from the department. The director of the department shall reconsider the determination and, if the pharmacy so requested, grant the pharmacy a hearing to be held within forty-five (45) days after the protest was filed, unless extended by agreement between the pharmacy and the director. The director shall issue a final decision within forty-five (45) days of the completion of the hearing. After a final decision by the director, a pharmacy's appeal of the director's final decision shall be to the Administrative Hearing Commission in accordance with section 208.156, RSMo 2000 and section 621.055, RSMo Supp. 2008.

(E) PRA Rates.

1. The PRA tax rate will be a uniform effective rate of one and twenty-hundredths percent (1.20%) with an aggregate annual adjustment, by the MO HealthNet Division, not to exceed five-hundredths percent (.05%) based on the pharmacy's total prescription volume.

2. Beginning January 1, 2019, the PRA tax rate will be a uniform effective rate of one and forty-three-hundredths percent (1.43%) with an aggregate quarterly adjustment, by the MO HealthNet Division, not to exceed one and five-tenths percent (1.5%) based on the pharmacy's total prescription volume.

3. Beginning July 1, 2022, the PRA tax rate will be a uniform effective rate of thirty-seven-hundredths percent (0.37%) with an aggregate quarterly adjustment, by the MO HealthNet Division, not to exceed one and five-tenths percent (1.5%) based on the pharmacy's total prescription volume.

4. The maximum rate shall be five percent (5%).

AUTHORITY: sections 208.201, 338.505, and 660.017, RSMo 2016. Emergency rule filed June 20, 2002, effective July 1, 2002, expired Feb. 27, 2003. Original rule filed July 15, 2002, effective Feb. 28, 2003. Amended: Filed Feb. 3, 2003, effective Aug. 30, 2003. Amended: Filed Nov. 3, 2003, effective April 30, 2004. Emergency amendment filed Sept. 12, 2008, effective Sept. 22, 2008, expired March 20, 2009. Amended: Filed Sept. 12, 2008, effective April 30, 2009. Amended: Filed July 1, 2009, effective Jan. 30, 2010. Emergency amendment filed Dec. 1, 2009, effective Jan. 1, 2010, expired June 29, 2010. Emergency amendment filed June 17, 2010, effective July 1, 2010, expired Dec. 27, 2010. Amended: Filed Dec. 1, 2009, effective June 30, 2010. Amended: Filed April 26, 2019, effective Nov. 30, 2019. Amended: Filed March 2, 2023, effective Oct. 30, 2023.*

**Original authority: 208.201, RSMo 1987, amended 2007; 338.505, RSMo 2002; and 660.017, RSMo 1993, amended 1995.*

13 CSR 70-20.330 Medication Therapy Management (MTM) Program

PURPOSE: This rule establishes the regulatory basis for the administration of the MO HealthNet Medication Therapy Management (MTM) program, including designation of professional persons who may perform medication therapy management services and defined covered services within the program.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Administration. The Medication Therapy Management (MTM) program shall be administered by the Department of Social Services, MO HealthNet Division. The MTM services covered, the program limitations, and the maximum allowable fees for all covered services shall be determined by the Department of Social Services, MO HealthNet Division, and shall be included in the pharmacy provider manual and provider bulletins, which are incorporated by reference and made a part of this rule as

published by the Department of Social Services, MO HealthNet Division, 615 Howerton Court, Jefferson City, MO 65109, at its website at dss.mo.gov/mhd/index.htm, September 1, 2015. This rule does not incorporate any subsequent amendments or additions.

(2) Persons Eligible. A person who is eligible for Title XIX (Medicaid) or Title XXI (State Children's Health Insurance Program) or Blind Pension and who meets certain disease-based criteria included in their health profile.

(3) Provider Participation. To be eligible for participation in the MO HealthNet MTM program, a provider must be a qualified Missouri licensed pharmacist and have an active MO HealthNet provider status, and must have successfully completed two (2) hours of ACPE (Accreditation Counsel for Pharmacy Education) accredited continuing education focused on the administration of MTM approved by the MO HealthNet Division.

(4) Medication Therapy Management Services. MTM Services are available to any currently eligible non-managed care MO HealthNet participant for whom the qualifying pharmacist receives a MO HealthNet directed electronic drug utilization review (DUR) message through a Point-of-Sale transaction. MO HealthNet uses a clinically based rules engine that juries which participants require MTM interventions based on nationally accepted evidence-based guidelines. Pharmacists are then messaged about only those participants who are identified for one (1) or more issues pertinent to the evidence-based criteria. The rules engine uses current nationally accepted evidence-based guidelines for clinically appropriate drug therapy, and applies this criteria to thirty-six (36) months of paid participant claims data which includes drugs, diagnoses, and procedures. When an eligible participant meets certain disease-based criteria a pharmacist may perform a wide variety of MTM services directed by MO HealthNet to address specific treatment needs, such as:

(A) Counseling participants on the importance of medication adherence (alerting participants to missed dosages and refills);

(B) Providing medication education;

(C) Providing self-care education for specific chronic conditions;

(D) Contacting physicians to schedule diagnostic testing;

(E) Contacting physicians to make drug therapy recommendations; or

(F) Connecting participants with other community-based resources as needed.

(5) The service is comprised of the following components:

(A) Assessing a participant's health status;

(B) Developing a medication treatment plan;

(C) Monitoring and evaluating a participant's response to therapy;

(D) Providing a comprehensive medication review to identify, resolve, and prevent medication-related problems;

(E) Documenting the care provided and communicating essential information to a participant's primary care providers;

(F) Providing oral education and training to enhance participant understanding and appropriate use of medications;

(G) Providing information, support services, and resources to enhance participant adherence to therapeutic regimens; and

(H) Coordinating and integrating MTM services within the broader health care services provided to a participant.

(6) Reimbursement. Pharmacists will receive the payment for participating in MTM. The payment is contingent upon the provider logging on to the electronic web tool to view, reserve, and complete interventions. Once an intervention is complete, providers will submit an electronic medical claim to MO HealthNet. The payment status of these claims will be reflected on the provider's remittance advice. The fee schedule is available at dss.mo.gov/mhd/providers/pages/cptagree.htm.

AUTHORITY: section 208.201, RSMo Supp 2013. Original rule filed July 30, 2015, effective Jan. 30, 2016.*

**Original authority: 208.201, RSMo 1987, amended 2007.*

13 CSR 70-20.340 National Drug Code Requirement

PURPOSE: This rule implements the requirement for the National Drug Code (NDC) for all medications administered in the clinic or outpatient hospital setting. The Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for certain physician-administered drugs.

(1) Drug charges submitted by providers on an electronic Professional or Institutional ASC X12 837 Health Care claim transaction or manually entered on a medical or outpatient claim into MHD's billing website eMOMED (www.emomed.com), are to be billed with a valid Healthcare Common Procedure Coding System (HCPCS) procedure code and a valid NDC for each medication, including injections, provided to the participant. Medical or outpatient claim lines submitted with a HCPCS procedure code without the corresponding NDC will be denied. For medical or outpatient claims correctly submitted with the appropriate HCPCS procedure code and the corresponding NDC, the system will automatically generate a separate drug claim for the NDC to process as a pharmacy claim, and will appear as a separate claim on your Remittance Advice. The corresponding line with HCPCS procedure code and NDC will be dropped from the medical or outpatient claim. If an NDC is not provided, the HCPCS procedure code will remain on the claim to report the denied line. For drugs without a valid HCPCS procedure code, revenue code 0250 "General Classification: Pharmacy" must be used with the appropriate NDC. Only drugs and items used during outpatient care in the hospital are covered. Take-home medications and supplies are not covered by MHD under the Hospital Program.

(2) Effective for dates of service on or after April 1, 2016, the MO HealthNet Division (MHD) will require the National Drug Code (NDC) for all medications administered in the clinic or outpatient hospital setting, to comply with federal law. MHD must collect the eleven- (11-) digit NDC on all outpatient drug claims submitted to MHD from all providers for rebate purposes in order to receive federal financial participation. Providers are required to submit their claims with the exact NDC that appears on the product dispensed or administered to receive payment from MHD. The NDC is found on the medication's packaging and must be submitted in the five (5) digit – four (4) digit – two (2) digit format. If the NDC does not appear in the five (5) digit – four (4) digit – two (2) digit format on the packaging, zero(s) (0) may be entered in front of the section that does not have the required number of digits.

(3) All drug claims shall be routed through an automated computer system to apply edits specifically designed to ensure effective drug utilization. The Preferred Drug List (PDL) and

clinical edits are designed to enhance patient care and optimize the use of program funds through therapeutically prudent use of pharmaceuticals. The edits are based on evidence-based clinical criteria and nationally recognized peer-reviewed information. This clinical information is paired with fiscal evaluation and then developed into a therapeutic class PDL recommendation. The PDL process incorporates clinical edits, including step therapies, into the MHD pharmacy program. Claims for drugs will automatically and transparently be approved for those patients who meet any of the system approval criteria. For those patients who do not meet the system approval criteria, the drugs will require a call to the MHD Drug Prior Authorization hotline at (800) 392-8030 to initiate a review and potentially authorize payment of claims. Providers may also use the CyberAccess tool to prospectively determine if a drug is a preferred agent or requires edit override, electronically initiate an edit override review, and to review a participant's MHD paid claim history.

(4) The quantity to be billed for injectables and other types of medications dispensed to MHD participants must be calculated as follows:

(A) Containers of medication in solution (for example, ampoules, bags, bottles, vials, syringes) must be billed by exact cubic centimeters or milliliters (cc or mL) dispensed, even if the quantity includes a decimal (e.g., if three (3) 0.5 mL vials are dispensed, the correct quantity to bill is 1.5 mL);

(B) Single dose syringes and single dose vials must be billed per cubic centimeters or milliliters (cc or mL), rather than per syringe or per vial;

(C) Ointments must be billed per number of grams even if the quantity includes a decimal;

(D) Eye drops must be billed per number of cubic centimeters or milliliters (cc or mL) in each bottle even if the quantity includes a decimal;

(E) Powder filled vials and syringes that require reconstitution must be billed by the number of vials;

(F) Combination products, which consist of devices and drugs, designed to be used together, are to be billed as a kit. Quantity will be the number of kits used;

(G) The product Herceptin, by Genentech, must be billed by milligram rather than by vial due to the stability of the drug; and

(H) Non-Vaccines for Children (VFC) Immunizations and vaccines must be billed by the cubic centimeters or milliliters (cc or mL) dispensed, rather than per dose.

(5) Radiopharmaceuticals used in radiologic procedures may be billed separately using the appropriate HCPCS code and/or the NDC representing the materials or agent used in the procedure. If available, MHD would prefer the NDC for reporting purposes. If the material or agent used does not have an NDC, the appropriate HCPCS code alone is acceptable. All HCPCS codes for radiopharmaceuticals are manually priced and must be billed with the manufacturer's invoice of cost attached to the claim.

AUTHORITY: sections 208.201 and 660.017, RSMo 2016. Emergency rule filed June 19, 2015, effective July 1, 2015, expired Dec. 28, 2015. Original rule filed July 1, 2015, effective Feb. 29, 2016. Amended: Filed Sept. 27, 2018, effective May 30, 2019. Amended: Filed Jan. 16, 2020, effective Aug. 30, 2020.*

**Original authority: 208.201, RSMo 1987, amended 2007 and 660.017, RSMo 1993, amended 1995.*