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

PROPOSED AMENDMENT

13 CSR 70-20.250 Prior Authorization of New Drug Entities or New Drug Dosage Form. The Department of Social Services is amending the purpose statement and sections (1), (2), (3), (4), (5), and (6).

PURPOSE: This amendment is to further clarify and add more detail to the new drug process.

PURPOSE: This rule outlines [the process by which] ***how*** *new drugs or new drug dosage forms of existing drugs may be subject to prior authorization [prior to]* ***before*** *payment by [Missouri's medical assistance program]* ***MO HealthNet Division (MHD)****.*

(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]* **are eligible to be covered, as defined in 13 CSR 70-20.030**, **and** shall comply with prior authorization requirements imposed by *[the division]* **MHD**, 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]* **MHD** and *[the division]* **MHD** eliminates the [*restriction*] **prior authorization** or makes a final determination to require **continued** [*restriction*] **prior authorization**. *[The division]* **MHD** shall consider known cost and *[use]* **utilization** data, medical and clinical criteria, and prudent utilization of state funds in the review. Interested parties may present clinical data to *[the division]* **MHD**.

(3) The review referenced in section (2) shall *[occur]* **begin** within thirty (30) business days after *[the division]* **MHD** receives notice through *[pricing updates]***the weekly national compendia file** of the availability of the drug entity on the market **and if the drug is eligible to be covered as defined in 13 CSR 70-20.030, whichever is later**. **The review shall take no more than forty-five (45) business days from the start of the review.** Upon completion of the review, *[the division]* **MHD** shall *[make the drug available for use by all MO HealthNet participants]* **remove the prior authorization requirements** or refer the new drug or new drug dosage form to the *[MO HealthNet Drug Utilization Review (DUR) Board]* **Prior Authorization Committee** with a recommendation for continued prior authorization. *[Staff]* **MHD** recommendations regarding continued prior authorization of a new drug or new drug dosage form shall be made in writing to the *[DUR Board]* **Prior Authorization Committee**. A copy shall be available to the public *[prior to]* **before** the *[DUR Board]* **Prior Authorization Committee** meeting in which the continued prior authorization is to be discussed.

(4) The *[DUR Board]***Prior Authorization Committee** shall consider any recommendations related to continued prior authorization **requirements** of a new drug or new drug dosage form *[at the next scheduled DUR Board meeting]***no later than one hundred ninety (190) calendar days after the new drug review is completed**. *[The division and the DUR Board may actively*

seek comments about the proposed restrictions]. The *[DUR Board]***Prior Authorization Committee** shall *[include five (5)]* **allow three (3)** minutes for any interested parties who have notified *[division in advance of]* **MHD before** the scheduled meeting to comment about such proposed *[restrictions]* **prior authorization requirements**.

(5) If the *[DUR Board]* **Prior Authorization Committee** finds that *[use]* **utilization** and cost data, pharmacoeconomic information, *[along with]* **and** medical and clinical implications of restriction*[,]* are documented**,** and *[restriction]* **prior authorization** is warranted, the *[DUR Board]* **Prior Authorization Committee** shall *[hold a public hearing regarding the continued restriction and]* make a recommendation to *[the division]* **MHD**. Such recommendation shall be provided to *[the division, in writing,]* ***MHD*** prior to the *[division]* **MHD** making a final determination. *[The division]***MHD** shall provide notice of the final determination through the Department of Social Services, *[MO HealthNet Division]* **MHD** website at *[dss.state.mo.gov/mhd], [provider bulletins, and updates to the provider manual]* **https://mydss.mo.gov/mhd/pharmacy-clinical-edits-pdl**.

(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]* **Prior Authorization Committee**.

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. Amended: Filed October 16, 2024.*

**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.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Social Services, Legal Services Division-Rulemaking, PO Box 1527, Jefferson City, MO 65102-1527, or by email to Rules.Comment@dss.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*