Regulatory Analysis Template

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Agency Name Iowa Medicaid HHS **Rule #:** *441 IAC 78.2(6)*

Iowa Code Section Authorizing Rule 249A.4

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

Date/Time: May 22, 2024, 11:30am- 12pm

Location: Microsoft Teams

Meeting ID: 218 701 087 784

Passcode: nnfJbK

Any interested person may submit written comments concerning this regulatory analysis. Written comments in response to this regulatory analysis must be received by the Department no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Contact Name

Joe Campos

Address

321 E. 12th St, Des Moines, IA, 50319

Email and/or phone number

compliancerules@idph.iowa.gov

Purpose and summary of proposed rule:

Iowa Administrative Code (IAC) currently permits a one-month supply of covered prescription and nonprescription medications for Iowa Medicaid members, excluding contraceptives which can be prescribed in three-month quantities *[441 IAC 78.2(6)]*.

a. Iowa Medicaid temporarily allowed an optional 90 days-supply on all medications from 3/19/2020 through 5/12/2023 due the Public Health Emergency (PHE).
    i. *The only safeguards during the PHE were from the prescriber and pharmacist using their discretion and professional judgement.*
    ii. *When the allowance was terminated in May 2023, the intent was always to re-implement with a Drug Utilization Review (DUR) recommendation (new safeguards) and rule change through the red tape review.*

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The proposed rule change would allow re-implementation of an optional 90 days-supply on a continuing basis for select, cost effective generic maintenance medications at the discretion of the prescriber while adhering to the guidelines provided by the Iowa Medicaid Drug Utilization Review (DUR) Commission.

DUR Review & Recommendation:

a. DUR Review: The proposal was presented at two DUR meetings February 1st & May 3rd, 2023 and public comment was sought from the medical and pharmacy associations on both dates
    iii. No concerns were shared and all DUR members were in favor
b. DUR recommendation: The 90 days-supply drug selection process – will include select, cost effective, generic medications from Medi Span maintenance drug categories
    iv. Proposed initial categories (select, generic drugs)
        - Blood pressure
        - Cholesterol lowering agents
        - Antidepressants
        - Diabetes mellitus
    v. List of Medications will be reviewed annually by the DUR and changes can be submitted to the DUR for review anytime throughout the year.
    vi. Exclusion criteria
        - Safety – e.g., risks associated with a particular class
        - Controlled substances
        - Narrow therapeutic index (NTI) drugs
        - Drugs subject to frequent dose adjustments
        - OTC drugs
        - Brand drugs
        - Prior Authorization drug categories (Clinical PA)
        - Nonpreferred or non-recommended drugs
        - Other therapeutic categories – antibiotics, ophthalmic, otic, and topical products
    vii. Dispensing fee – Medicaid would pay pharmacy for one dispensing fee per 90 days-supply billed rather than three (further cost saving details in section below).
    viii. Copayment - member gets charged one copay (if applicable) per 90 days-supply billed.
    ix. Member exclusions - none
    x. Initial fill – quantity would be at the discretion of prescriber, but consideration should be given to dispensing less than a 90 days-supply with the initial fill when starting members on new medications or with dose adjustments to minimize waste.

Surrounding states that allow 90 days-supply prescription quantities for Medicaid members include: Nebraska, Missouri, Kansas, Minnesota, and Wisconsin.

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Analysis of Impact of Proposed Rule

1. Persons affected by the proposed rule
    - Classes of persons that will bear the costs of the proposed rule:

1. Pharmacies may be affected by a decrease in revenue due to receiving only 1 dispensing fee versus 3 over a 3-month period, but the proposed change is only allowed for certain medications and it's also not a requirement for members, it's optional.

    a. Classes of persons that will benefit from the proposed rule:

1. Pharmacies may benefit as a decrease in the number of prescriptions being dispensed allowing additional time to provide other revenue generating services such as immunizations and point-of-care testing.

2. Iowa Medicaid and Managed Care Organizations

3. Iowa Medicaid members: Fee-For-Service and Managed Care Plan members

4. Providers treating Iowa Medicaid members

2. Impact of the proposed rule, economic or otherwise, including the nature and amount of all the different kinds of costs that would incur
    a. Quantitative description of impact:

a. Member/Patient
    i. FFS members – when applicable, only paying one, $1 copay versus three $1 copays
    ii. May reduce patient transportation costs with fewer trips to the pharmacy
b. Iowa Medicaid
    i. Dispensing Fee Savings = $10.38. Medicaid would only pay one fee of $10.38 for dispensing a 90 days-supply vs 3 fees = $31.14 over the span of 3 months. Cost savings: $20.76
    ii. Estimated annual cost savings during PHE for Iowa Medicaid and Managed Care Organizations (State & Federal) = **$7,040,048**
c. Pharmacy Providers
    i. Dispensing Fee Loss= $10.38. Providers would only receive one fee of $10.38 for dispensing a 90 days-supply vs 3 fees = $31.14 over the span of 3 months. Fee difference = $20.76.

    b. Qualitative description of impact:

a. Member/Patient
    i. Improve patient compliance, resulting in better health outcomes for chronic medical conditions

ii. Recent member and provider complaints after temporary allowance ended.

b. Iowa Medicaid
   i. Consistent with commercial payer guidelines

c. Pharmacy Providers
   i. Potential impact to provide more clinical services, such as immunizations, point-of-care testing, medication therapy

3. Costs to the state
   a. Implementation and enforcement costs borne by the agency or any other agency:

Programming will need to be done for FFS and the MCOs. There will not be a fiscal impact to get this done.

   b. Anticipated effect on state revenues:

1. Dispensing Fee = $10.38. Medicaid would only pay one fee of $10.38 for dispensing a 90 days-supply vs 3 fees = $31.14 over the span of 3 months. Cost savings per prescription: $20.76
   a. Estimated Annual cost savings on dispensing fees during PHE for Iowa Medicaid and Managed Care Organizations (State AND Federal) = **$7,040,048**

4. Comparison of the costs and benefits of the proposed rule to the costs and benefits of inaction

Refer to section 2 – Impact of Proposed Rule

5. Determination if less costly methods or less intrusive methods exist for achieving the purpose of the proposed rule

No alternative methods have been considered.

6. Alternative methods considered by the agency
   a. Description of any alternative methods that were seriously considered by the agency:

No alternative methods have been considered.

   b. Reasons why they were rejected in favor of the proposed rule:

N/A.

Small Business Impact

If the rule will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rule on small business:

- Establish less stringent compliance or reporting requirements in the rule for small business.
- Establish less stringent schedules or deadlines in the rule for compliance or reporting requirements for small business.
- Consolidate or simplify the rule's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rule for small business.
- Exempt small business from any or all requirements of the rule.

If legal and feasible, how does the rule use a method discussed above to reduce the substantial impact on small business?

This change does not pose strict compliance with the new rule as the 90 days-supply fill will be optional for the member. It does not require the member to fill their prescriptions as a 90 days-supply. This change also only impacts certain classes or groupings of medications. Pharmacies will still gain a dispensing fee on every prescription filled, regardless of quantity dispensed.

Text of Proposed Rule:

Amend rule **441—78.2(6)** as follows:

Quantity prescribed and dispensed.

a. *Quantity prescribed.* When it is not therapeutically contraindicated, the legally qualified practitioner shall prescribe ~~not less than~~ a one-month supply of covered prescription and nonprescription medication. Medications listed on the 90-day generic maintenance supply drug list published on the department's website and ~~C~~contraceptives may be prescribed in three-month quantities.

b. *Quantity dispensed.* A prescribed drug must be dispensed in the quantity specified on the prescription unless prohibited by the Medicaid pharmacy program requirements, the pharmacy is using unit dose dispensing, the specified quantity is not available in the pharmacy when the prescription is dispensed or in a quantity permitted pursuant to Iowa Code section 155A.27.

c. Prescription refills. NO CHANGES.

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