DMAHS Advance Notice of Proposed Rulemaking:

Notice of Proposed Amendments: N.J.A.C. 10:51, Pharmaceutical Services

To whom it may concern:

This notice provides advance notice that the New Jersey Department of Human Services, Division of Medical Assistance and Health Services, will be publishing a proposed rulemaking to amend N.J.A.C. 10:51, Pharmaceutical Services.

There are currently three subchapters and seven appendices to N.J.A.C. 10:51.

N.J.A.C. 10:51-1, Pharmaceutical Services, currently provides the policies related to the provision of pharmaceutical services to New Jersey Medicaid/NJ FamilyCare beneficiaries. This subchapter includes an introduction to pharmaceutical services, participation of eligible providers and conditions for participation, as well as program restrictions that would affect payment. Details are provided on the basis of payment, discounts, dispensing fees, compounded and generic prescriptions, and the providers' usual and customary or advertised charge. The subchapter lists the covered and non-covered pharmaceutical services, prior authorization requirements, quantity, dosage and direction for medication, and personal contribution to care requirements for NJ FamilyCare-Plan C and copayment requirements for NJ FamilyCare Plan D. Requirements related to prescriptions, including telephone-rendered prescriptions, original prescriptions, changes or additions to the original prescription, and refills are provided. Also described in this subchapter is the Prescription Drug Price and Quality Stabilization Act, Drug Efficacy Study Implementation (DESI)/Identical Related Similar (IRS) drugs, drug manufacturers rebate agreement, and rules for bundled drug service. The last sections provide the rules for claim submission, the point-of-sale (POS) claims adjudication system, prospective drug utilization review and the medical exception process.

N.J.A.C. 10:51-2, Pharmaceutical Services to Medicaid/NJ FamilyCare Fee-For-Services Beneficiaries in a Nursing Facility, currently contains the rules related to the provision of pharmaceutical services to beneficiaries in a nursing facility, participation of eligible providers, and conditions for participation, as well as program restrictions. It also covers the rules for basis of payment, compounded prescriptions, generic prescriptions, discounts, and dispensing fees. The subchapter also contains rules related to the covered and non-covered pharmaceutical services, quantity of medications dispensed, dosages and directions, prescriptions and medication orders rendered by telephone or technological devices, changes or additions to the original prescriptions and refills. Also described in this subchapter are rules related to the Prescription Drug Price and Quality Stabilization Act, the Drug Efficacy Study Implementation (DESI), Drug manufacturers rebate agreement, and bundled drug service. The last sections provide the rules for claim submission, Point-of-sale (POS) claims adjudication system and the Prospective Drug Utilization Review (PDUR) program.

N.J.A.C. 10:51-3, Consultant Pharmacist Services, currently sets forth the services provided by a consultant pharmacist, the definition of a consultant pharmacist, as well as the qualifications required to fulfill the responsibilities of a pharmacist. Finally, the responsibilities of a pharmacist acting as a consultant are described.

Appendix A, Drug Efficacy Study Implementation (DESI), contains the drugs designated for withdrawal from the market by the United States Food and Drug Administration.

Appendix B, Upper Payment Limits for Maximum Allowable Cost (MAC) Drugs, lists the multiple source drugs designated by the Centers for Medicare and Medicaid Services (CMS).

Appendix C is Form FD-70, the Pharmacy Provider Certification Statement.

Appendix D, the Fiscal Agent Billing Supplement, contains billing instructions for providers.

Appendix E, Electronic Media Claims (EMC) Manual, contains instructions to providers regarding the submission of claims via electronic media.

Appendix F, Medicaid Rebate Program, is a list of drug manufacturers who have a rebate agreement established in accordance with federal law.

Appendix G, Notification of Pharmaceutical Services in Nursing Facilities, is an agreement form to be completed by pharmacies servicing nursing facilities in accordance with the requirements of N.J.A.C. 10:51-2.7.

A comprehensive review of the chapter has been completed and many areas of the chapter have been identified as requiring amendments and some reorganization to reflect the most current practices of the Division of Medical Assistance and Health Services and applicable State and Federal laws.

The proposed amendments will:

1. Add the following sections to N.J.A.C. 10:51-1 addressing:
    - A comprehensive list of updated definitions;
    - State Upper Limits for multi-source drugs;
    - The 340B Drug Discount Program;
    - Professional fee;
    - Early Prescription Refills;
    - Mandatory Generic Substitution of Brand-Name Multi-Source Drugs;
    - Mandatory Generic Substitution of Brand-Name Multi-Source Drugs – Exceptions;
    - Third Party Liability (TPL) Payments;
    - Medicare Part B-Covered Drugs;

- Medicaid/NJ FamilyCare beneficiaries enrolled in the Medicare Part D Drug Benefit Program;
- NJ Prescription Monitoring Program (NJPMP);
- Practitioner-Administered Drugs;
- Automatic Prescription Drug Refill Restrictions; and
- Affordable Care Act (ACA) Requirements.

2. Add the following sections to N.J.A.C. 10:51-2 addressing:
   - State Upper Limits for multi-source drugs;
   - Regression or Volume Discounts;
   - Professional fee;
   - Provider's Usual and Customary Charge or Advertised Charge;
   - Services Requiring Prior Authorization;
   - Mandatory Generic Substitution of Brand-Name Multi-Source Drugs;
   - Mandatory Generic Substitution of Brand-Name Multi-Source Drugs – Exceptions;
   - Third Party Liability (TPL) Payments;
   - Medical Exception Process (MEP);
   - Medicare Part B-Covered Drugs;
   - Medicaid/NJ FamilyCare beneficiaries enrolled in the Medicare Part D Drug Benefit Program;
   - NJ Prescription Monitoring Program (NJPMP); and
   - Affordable Care Act (ACA) Requirements.

3. Make technical amendments intended to update contact information; correct grammar, spelling, and punctuation; improve the organization of the chapter; correct codification errors and/or cross-references; eliminate unnecessary, duplicative, and/or superseded text; and clarify existing program rules.

This notice provides you with an opportunity to comment on the upcoming amendments by **August 18, 2023**.

NOTE: You will be notified of the publication date of the proposed rulemaking(s) once the date is finalized by the Office of Administrative Law, which will include a 60-day public comment period during which formal comments will be accepted.

Please send any comments that you have regarding this advance notice of the upcoming proposed rulemaking by the date indicated above to:

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General feedback or comments on any Medicaid/NJ FamilyCare rule or program is always welcome and can be submitted in the manner described above for consideration and possible inclusion in future rulemakings.

Thank you for your interest in the Medicaid/NJ FamilyCare program.