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The Medical Society of New Jersey (MSNJ) would like to take this opportunity to comment concerning the Departments proposed re-adoption of the Health Maintenance Organization regulation. MSNJ appreciates DOBI's efforts to codify that emergency and urgent care services must be covered under a health benefits plan in accordance with a provider agreement. We would like to also offer suggestions for further implementation.

New Jersey's physicians continually try to ensure that patients receive the most responsive diagnosis relevant to specific individual health care. Unfortunately, a physician's recommended treatment or medication is not always found to be a "covered" health care service under various insurance plan interpretations. These HMO regulations were intended to provide physicians and patients with significant protections from managed care abuses without erecting barriers to quality health care. Unfortunately interpretations of the regulations over time have jeopardized the original intent of the law. We hope the Department offers our proposed language to ensure that the regulations are properly stated so that the true intent of the law is followed.

MSNJ had identified two areas where we believe clarification of the original intent of the regulations is critical to ensuring clinically based quality care access of medications for patients in New Jersey.

**8:38-18.1 – Development of Formulary**

**Step Edits or Try and Fail Requirements** – The current language intends to ensure that formularies are developed and adjudicated based on "clinically meaningful therapeutic advantages in terms of safety, effectiveness, or clinical outcome." Reality dictates, however, that physician prescribed medications are routinely denied by HMO's and patients are forced to try and fail a number of less effective drugs under a process called "step therapy" or "pre-certification." This design has forced many New Jersey patients from being treated with a clinically proven appropriate agent until a number of substitutes are first tried and failed. Furthermore, in many instances, these HMO recommended "step therapy" or "pre-certification" prerequisite choices are not FDA approved for the treatment requested for a given patient.

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Plans can continue to encourage utilization towards on-formulary agents and generics through their current multi-tier co pay designs without circumventing physicians' good medical judgment with step edit designs for a given patient.

We suggest that the following language be added to the development of formulary section to clarify the regulation's intent:

**"A formulary shall not include a "step edit" or a requirement to try and fail other formulary drugs first."**

### **8:38-18.2 – Non-formulary Medications**

**Certification of Necessity** – Subsection (c) 2 of this section requires that a "prescribing healthcare provider state that all formulary medications used to treat a disease must have been ineffective in the treatment of the covered person's disease or condition, or all such medications have caused or are reasonably expected to cause adverse or harmful reactions to the covered person."

This is an area where physicians and pharmacists have seen a significant increase in the number of prior authorization denials for medications used for clinically appropriate indications. Denials by plans are often not based on any clinical reasons but simply an attempt to enforce their step edit designs.

Plans have even directed physicians to try and fail non FDA approved medications for a specific diagnosis before approving the physician's clinically recommended medication. Additionally, plans have continued to change approval criteria making it difficult to follow these protocols and have also denied patients who have a positive history on a particular drug from continuing dosage.

MSNJ recommends the addition of the following underlined language be included into Subsection (c) 2 to reduce this abuse.

"The prescribing healthcare provider states that **the patient is currently well managed on a therapy, or the physician states the drug is "medically necessary," or** all formulary medications used to treat a disease state have been ineffective in the treatment of the covered person's disease or condition, or all such medication have cause or are reasonably expected to cause adverse or harmful reactions, **or would be less effective** in the covered person."

Thank you again for the opportunity to provide comments to improve the intent of these regulations.

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