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NYS has New Law to Provide Patient Protections around the Use of Step Therapy (Fail First) Protocols by Health Insurance Companies

Frequently Asked Questions about the New Law

I. What are Step Therapy (Fail First) Protocols?

ANSWER:

- Step Therapy protocols, also known as "Fail First" protocols, are policies that establish a specific sequence in which prescription drugs for a medical condition are approved for coverage by a health insurance plan for a patient.

II. What is the new step therapy reform law in NYS?

ANSWER:

- The new law is Chapter 512 of the Laws of 2016. It adds new protections for patients when they are required to use step therapy protocols and includes an improved process for a patient to appeal a required step therapy protocol. To view the full text of the new law, please use the following link: http://nyassembly.gov/leg/?default_fld=&leg_video=&bn=S03419&term=2015&Summary=Y&Text=Y

III. Which health insurance plans does the new law apply to?

ANSWER:

- The new law applies to commercial health insurance plans, subject to Articles 32 and 43 of the Insurance Law as well as plans certified under Article 47 (municipal cooperative health benefit plans). Further the law applies to plans certified under Article 44 of the public health law (HMOs) and this includes Medicaid Managed Care plans. The new law does not apply to Medicare (federal) plans, Medicaid fee for service or to self-insured, ERISA plans or labor benefit plans.

IV. What specifically does the law require of health insurance plans?

ANSWER:

The new law:

- Requires health insurers to utilize evidence-based and peer reviewed clinical review criteria that also takes into account the needs of atypical patient populations when establishing step therapy protocols.
- Provides a standardized appeals process that can be used by a patient's physician or other prescriber to request a step therapy override if he/she believes the drug(s) being required by the health insurer is not in the best interest of the patient.
- Requires health insurers, when conducting the review of a request for a step therapy override, to utilize recognized evidence-based and peer reviewed clinical review criteria appropriate for the patient and his/her medical condition.
- Requires health insurers to disclose their clinical review criteria relating to a step therapy override determination to health care providers and patients, upon written request.

V. How does the improved review process work under the new law?

ANSWER:

- The utilization review (appeal) process in the law states that a health insurer (utilization review agent) shall grant a step therapy protocol override upon receipt of information that includes supporting rationale and documentation from a health care provider which demonstrates that the drug(s) being required by the health insurer:
    - Is contraindicated or will likely cause an adverse reaction by physical or mental harm to the patient;
    - Is expected to be ineffective based on the known clinical history and conditions of the patient and his/her drug regimen;
    - Has been tried by the patient or another prescription drug(s) in the same pharmacologic class or with the same mechanism for action and such drug(s) was discontinued due to a lack of efficacy or effectiveness, diminished effect or an adverse event;
    - Should not be required because the patient is stable on a drug other than the drug being required by the insurer; or
    - Is not in the best interest of the patient because it will likely cause a significant barrier to a patient's adherence with his/her plan of care, will likely worsen a comorbid condition of a the patient, or will likely decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.

**The standards included in the new law for the process listed above do not prevent a health insurer from requiring a patient to try an AB-rated generic equivalent drug prior to authorizing coverage for the equivalent brand name prescription drug being ordered by a prescriber.*

VI. What are the timeframes included in the new law related to the utilization review (appeals) process?

ANSWER:

- Health insurers must respond to utilization review requests within 72 hours, or for emergencies, within 24 hours.
- An emergency is defined as a medical condition that places the health of the patient (insured) in serious jeopardy without the prescription drug or drugs prescribed by the patient's health care provider.
- Importantly, upon a determination that the step therapy protocol should be overridden the health plan shall authorize immediate coverage for the prescription drug prescribed by the patient's health care provider.

VII. What if health insurers do not respond to the utilization review request within the required timeframes detailed above?

ANSWER:

- If the insurer fails to respond within the required timeframes, the appeal (override) of the required step therapy protocol will be granted in favor of the patient.

VIII. What if a patient loses his/her utilization review request?

ANSWER:

- If a patient (or a health care provider on his/her behalf) receives an adverse determination to a step therapy protocol override request, he/she has the right to an external appeal to be reviewed by an independent external appeal agent, under Articles 49 of the State Insurance and Public Health laws. For more information on the right to external appeals and process to seek such an appeal, please go to: http://www.dfs.ny.gov/insurance/extapp/extappqa.htm

IX. What is the effective date of the new law?

ANSWER:

- The new law took effect on January 1, 2017, however it applies to health insurance plans delivered, issued for delivery issued or renewed after that date.
- Importantly, we are awaiting further guidance from the NYS Insurance Department (DFS) working with the State Health Department (DOH) on the implementation and enforcement of the new law but it is our understanding that for individual plans, the new law would not be applicable until policy year 2018 commencing January 1, 2018 since the 2017 plans were all approved prior to the new year. However, group plans are approved on a rolling basis so as this year goes on more and more will be

subject to the new law. *We will work with DFS and DOH to better under this schedule and work with them on the roll out of the new law.*

X. What role does NY's Insurance Department (DFS) and State Health Department (DOH) play in implementing the new law?

ANSWER:

- Under the new law, the Superintendent of DFS is authorized to promulgate any rules or regulations necessary for the timely implementation of the law. DFS is expected to develop model contract language to incorporate the new step therapy requirements along with a circular letter to the plans to assist with implementation. *Again however, we await further information from DFS on their implementation plans and enforcement activities related to the new law but expect DFS and DOH jointly to issue guidance to the plans that each oversee.*

XI. Where can patients and providers go to file complaints related to health insurance companies not being compliant with state laws?

ANSWER:

- **For Commercial Insurance: The Department of Financial Services Hotline:**
  http://www.dfs.ny.gov/consumer/fileacomplaint.htm
  (212) 480-6400 or toll-free (800) 342-3736 (Monday through Friday, 8:30 AM to 4:30 PM)

- **For Medicaid Managed Care Plans: The New York State Medicaid Managed Care Hotline:**
  managedcarecomplaint@health.state.ny.us
  1-800-206-8125

- **For all Health Insurance-Related Issues: NYS Attorney General Health Care Bureau Hotline:**
  http://www.ag.ny.gov/bureau/health-care-bureau
  The Bureau's Health Care toll-free Helpline, 1-800-428-9071

For questions related to this new law, please contact Marcy Savage, Partner at Reid, McNally & Savage, LLC at marcys@lobbywr.com