**FACT SHEET**

New Step Therapy Reform Law in New York State

What Health Care Providers Need to Know

On December 31, 2016, Governor Andrew Cuomo signed legislation into law to add new protections for patients when their health insurance plans require them to go through “step therapy”, or “fail first”, protocols when accessing prescription drugs for a medical condition(s). Below are answers to 9 key questions to help physicians, and other health care providers, better understand the new law, whether it applies to their health insurance plan and the new protections the law provides.

**Q1. What are Step Therapy (Fail First) Protocols?**

**A1.** As you are likely aware, step Therapy protocols, also known as “Fail First” protocols, are policies that establish a specific order in which prescription drugs for a medical condition are approved for coverage for a patient.

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**Q2. What is the new step therapy reform law in NYS?**

**A2.** The new law (Chapter 512 of the Laws of 2016) adds increased protections for patients in the development and use of step therapy protocols by health insurers and includes an improved process for a patient to appeal it. To view the full text of the new law, go to:

<http://nyassembly.gov/leg/?default_fld=&leg_video=&bn=S03419&term=2015&Summary=Y&Text=Y>

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**Q3. Which health insurance plans does the new law apply to?**

**A3.** The new law applies to state-regulated commercial health insurers, HMO plans, Medicaid Managed Care plans and Child Health Plus plans. The new law does **not** apply to Medicare, Medicaid fee for service

or “self-insured” plans, which are exempted by the federal Employee Retirement Income Security Act of 1974 (ERISA).

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**Q4. What specifically does the law require of health insurance plans?**

**A4.** The new law does the following:

* Requires health insurers to utilize evidence-based and peer reviewed criteria that takes into account the needs of atypical patients when creating step therapy policies and to also use evidence-based, peer-reviewed criteria when reviewing of a request for a step therapy override (appeal);
* Provides an improved appeals process that can be used by a patient’s prescriber

to request an override of step therapy 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 to disclose their clinical review criteria relating to a step therapy override determination, to health care providers and patients, upon written request.

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**Q5. How does the improved appeals process work under the new law?**

**A5.** The new appeals process requires health insurers to make an exception if a patient’s health care provider submits information which demonstrates the following about the drug(s) being required by the plan:

* + **T**ried by Patient and was Ineffective. The drug was tried and discontinued due to lack of efficacy or effectiveness, diminished effect or adverse event;
	+ **A**dverse Reaction Concerns. The drug is contraindicated or will likely cause an adverse reaction by physical or mental harm to the patient;
	+ **P**atient Best Interest Concerns. The drug is not in the best interest of the patient because it will likely cause a significant barrier to adherence, likely worsen a comorbid condition, or likely decrease the patient’s ability to achieve/ maintain functional ability in daily activities;
	+ **E**xpected to be Ineffective. The drug will likely be ineffective based on the known clinical history and conditions of the patient and his/her drug regimen; or
	+ **S**tability of Patient Impacted. The drug should not be required because the patient is stable on a drug other than the drug being required by the insurer.

\*Note, the law does not prevent an insurer from requiring a patient to try an AB-rated generic prior to authorizing coverage for the drug that was originally prescribed.

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**Q6. What are the timeframes included in the new law related to the appeals process?**

**A6.** The new law requires insurers to adhere to the following timeframes:

* Health insurers must respond to appeal requests within 72 hours, or for emergencies (placing patient’s health in serious jeopardy), within 24 hours.
* Upon a determination that the step therapy protocol should be overridden the health plan must authorize **immediate** coverage for the prescription drug.
* 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.

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**Q7. What if a patient loses his/her appeal request?**

**A7.** If a patient (or a health care provider on his/her behalf) receives a negative determination to a step therapy protocol appeal request, he/she has the right to an external appeal to be reviewed by an independent external appeal agent. 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>

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**Q8. What is the effective date of the new law?**

**A8.** The new law took effect on January 1, 2017; however, it applies to health insurance plans delivered, issued for delivery, or renewed **after** that date. By January 1, 2018, all plans that the law applies to (see FAQ #3) must comply. In May 2017, the state Insurance Department (DFS) issued guidance on the new law: http://[www.dfs.ny.gov/insurance/health/step\_therapy\_legislation\_qa.htm](http://www.dfs.ny.gov/insurance/health/step_therapy_legislation_qa.htm)

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**Q9. Where can health care providers go to file complaints related to health insurance companies not being compliant with this and other state laws?**

**A9.** For more information, please refer to the following:

* **For Commercial Insurance: The Department of Financial Services Hotline:**

<http://www.dfs.ny.gov/consumer/fileacomplaint.htm/> (800) 342-3736

* **For Medicaid Managed Care Plans: The New York State Medicaid Managed Care Hotline:** managedcarecomplaint@health.state.ny.us/ (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, (800) 428-9071

***For more information or questions on the new law, please contact:***