**FACT SHEET FOR NY PATIENTS ABOUT NEWLY PASSED “STEP THERAPY/FAIL FIRST” REFORM LAW**

**10 Key Questions Answered**

On December 31, 2016, Governor Andrew Cuomo signed a bill into law to add new protections for patients when their health insurance plans require them to go through a process known as “step therapy” or “fail first”, when filling a prescription from their health care provider, for a medical condition(s). Below are answers to 10 key questions to help patients/consumers better understand the new law, whether it applies to their health insurance plan and the new protections the law provides.

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**Q1. What is “Step Therapy” (Fail First)?**

**A1.** “Step Therapy”, also known as “Fail First”, are policies that establish a specific order in which prescription drugs for a medical condition are approved for coverage by a health insurance plan for a patient. In other words, before a patient can access a drug that is prescribed, a health insurer may first force them to try and fail on one or more alternative drugs, under Step Therapy rules.

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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 when step therapy rules are imposed by health insurers and includes an improved process for patients to appeal.

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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 insurance plans, 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 use evidence-based and peer reviewed information that considers the needs of patients when imposing step therapy rules;
* Provides an improved appeals process that can be used by a patient’s physician or other 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.

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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 decision that Step Therapy should be overridden the health plan must provider **immediate**

coverage for the prescription drug.

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**Q7. What if health insurers do not respond to the appeal request within the required timeframes detailed above?**

**A7.** If the insurer fails to respond within the required timeframes, the appeal (override) will be granted **in favor** of the patient.

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**Q8. What if a patient loses his/her appeal request?**

**A8.** If a patient’s (or a health care provider on his/her behalf) appeal is denied, he/she has the right to an external appeal to be reviewed by an independent agent. For more information on the right to external appeals, and the process to file an appeal, please go to: <http://www.dfs.ny.gov/insurance/extapp/extappqa.htm>

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**Q9. What is the effective date of the new law?**

**A9.** The new law took effect on January 1, 2017, however it applies to new health insurance plans sold, or those renewed, **after** that date. By January 1, 2018, all plans that the law applies to (see FAQ #3) must comply.

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**Q10. Where can patients and providers go to file complaints if their health insurance company doesn’t comply with the law?**

**A10. Where you buy your plan, determines where you file your complaint:**

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

<http://www.dfs.ny.gov/consumer/fileacomplaint.htm/> (800) 342-3736 , Monday – Friday,8:30am-4:30pm9

* 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

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