TRINIDAD NAVARRO
COMMISSIONER

STATE OF DELAWARE
DEPARTMENT OF INSURANCE

# DOMESTIC AND FOREIGN INSURERS BULLETIN NO. 165

**TO:** **INSURERS, HEALTH SERVICE CORPORATIONS, AND MANAGED CARE ORGANIZATIONS THAT DELIVER OR ISSUE FOR DELIVERY IN THIS STATE INDIVIDUAL AND GROUP INSURANCE POLICIES OR PLANS SUBJECT TO REGULATION UNDER TITLE 18 OF THE DELAWARE CODE**

**RE:** **STEP THERAPY EXCEPTIONS**

**DATED:** **March 24th, 2026**

---

The Department issues this Bulletin to reinforce its position regarding the step therapy exceptions processes required by 18 *Del. C.* §§ 3381 and 3591 and to address questions that have arisen regarding the scope of the statutory exclusions in subsection (e). The Department has reviewed carrier practices and determined that clarification is necessary to ensure uniform and accurate implementation of these provisions.

## Background

HS 1 for HB 105, enacted by the General Assembly and effective March 18, 2020, added new Sections 3381 and 3591 to Title 18 of the Delaware Code, establishing a standardized, patient-centered framework governing the use of step therapy protocols in Delaware. These statutes require carriers to maintain a clear and accessible process for requesting exceptions to step therapy requirements and to identify specific clinical circumstances in which an exception must be granted. The provisions also ensure that a health-care provider's clinical judgment remains central to treatment decisions by preserving the ability to request an override when step therapy is not medically appropriate for a particular patient.

Both sections include a narrow exclusion in subsection (e) permitting carriers to require a patient to try an AB-rated generic equivalent before covering the equivalent branded prescription drug, and reaffirming that providers may prescribe a medically necessary drug notwithstanding step therapy requirements. The exclusion under subsection (e) reads as follows:

> e) This section shall not be construed to prevent any of the following:
>
> > (1) An insurer, health plan, or utilization review entity from requiring a patient to try an AB-rated generic equivalent prior to providing coverage for the equivalent branded prescription drug.

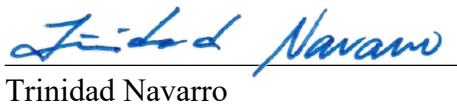
(2) A health-care provider from prescribing a prescription drug that is determined to be medically necessary.

It has come to the Department's attention that carriers may have expanded the interpretation of the statutory exception in subsection (e) beyond the plain language enacted by the General Assembly, applying it to biologics and their biosimilars. Biologics are not "branded prescription drugs," nor do they have "AB-rated generic equivalents." Therefore, the language in (e)(1) does **not** apply to biologics.

While the Department understands the similarities between brands/generics vs. biologics/biosimilars, the statutory language passed by the General Assembly is explicit in the scope of its exception. Therefore, it is the Department's position that it is inappropriate for a carrier to expand this language to include biologics and their biosimilars when interpreting or implementing Sections 3381 and 3591.

Questions about this Bulletin should be emailed to compliance@delaware.gov.

This Bulletin shall be effective immediately and shall remain in effect unless withdrawn or superseded by subsequent law, regulation or bulletin.



Trinidad Navarro
Delaware Insurance Commissioner