



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 24, 2026

REVISED: October 20, 2026

The Department issues this revised Bulletin to clarify the proper interpretation of the step therapy exception provisions in 18 *Del. C.* §§ 3381 and 3591 and to update prior guidance in light of statutory changes enacted since the publication of the original Bulletin. The Department has reviewed carrier practices and determined that additional clarification is necessary to ensure uniform and accurate implementation of these statutes, particularly regarding the limited exceptions in subsection (e) and the treatment of interchangeable biologics and biosimilars under recently enacted law.

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.

Bulletin 165 originally clarified that this exception applies only to branded prescription drugs with AB-rated generics and does not extend to biologics, which have neither “branded prescription drug” status nor “AB-rated generic equivalents.” As originally enacted, paragraph (e)(1) therefore did **not** apply to biologics or biosimilars.

Since then, the General Assembly enacted [House Bill 429](#), effective July 23, 2026, which amended the step therapy exception provisions to expressly allow carriers to require trial of an interchangeable biological product or biosimilar before providing coverage for the corresponding brand name prescription reference product drug. This statutory update expands, but does not replace, the original exception categories, and the Department is issuing this revised Bulletin to reflect this legislative change while reaffirming the limitations of subsection (e) as originally enacted.

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

Note: This Bulletin is intended solely for informational purposes. It is not intended to set forth legal rights, duties, or privileges, nor is it intended to provide legal advice. Readers should consult applicable statutes and rules and contact the Delaware Department of Insurance if additional information is needed.