

**Explanation of Changes Reflected in the Chairman’s  
Amendment in the Nature of a Substitute to  
H.R. 5343, *Ensuring Patient Access to Critical Breakthrough Products Act***

September 16, 2025

The Chairman’s amendment in the nature of a substitute includes the following changes to H.R. 5343 as introduced:

1. Page 2, line 18: Strike “,” and insert “—“(i)”.
2. Page 2, line 25: Strike “, or” and insert “; “(ii)”.
3. Page 3, line 3: Strike “;” and insert “; or “(iii) which is prohibited from being paid under section 1899D(d);”.
4. Page 4, line 3: Strike “Designation of”.
5. Page 4, line 5: Insert “(in a form and manner specified by the Secretary)” after “application”.
6. Page 5, line 1: Strike “such” and insert “the Public Health Service”.
7. Page 5, line 4: Insert “(1)” after “1862(a)”.
8. Page 5, line 11: Insert “The device is not a clinical diagnostic laboratory test.”.
9. Page 6, line 3: Strike “(d)” and insert “(d) Payment prohibition.—No payment may be made under part A or B with respect to a breakthrough device furnished to an individual— “(1) that is furnished more frequently than as specified in the Food and Drug Administration-approved labeling for such device (or, in the case such device has no frequency so specified, that is furnished more frequently than the Secretary determines appropriate); or “(2) in the case of such a device that is furnished by a provider of services or supplier that the Secretary determines has an aberrant billing pattern with respect to such device or that is otherwise an outlier with respect to the furnishing of such device compared to similarly situated providers of services and suppliers, is not reasonable and necessary with respect to the individual for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”.
10. Page 6, line 3: Insert “(e)” before “Reports”.
11. Page 6, line 15: Strike “(e) Review of aberrant billing.—The Secretary may conduct a review of the medical necessity and reasonableness of a breakthrough device furnished by a provider of service or supplier that the Secretary determines has an aberrant billing pattern with respect to such a device or otherwise is an outlier with respect to the furnishing of such device compared to similarly situated providers of services and suppliers.”.
12. Page 7, line 8: Insert “on a national basis” after “covered”.
13. Page 7, line 8: Strike “this title” and insert “Part A or B”.
14. Page 7, line 19: Strike “2025” and insert “2026”.
15. Page 7, line 20: Strike “2030” and insert “2031”.