SENATE FILE NO. SF0047

Clinical laboratory regulation-direct to consumer exception.

Sponsored by: Senator(s) Case and Representative(s) Larsen

A BILL

for

- 1 AN ACT relating to professions and occupations; providing
- 2 an exception for the collection and testing of human
- 3 specimens by clinical laboratories; requiring rulemaking
- 4 authority; and providing for effective dates.

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6 Be It Enacted by the Legislature of the State of Wyoming:

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- 8 **Section 1.** W.S. 33-34-107 by creating a new
- 9 subsection (e) is amended to read:

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- 33-34-107. Acceptance, collection, identification and
- 12 examination of specimens.

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- 14 (e) This section shall not apply to a direct to
- 15 consumer test. For the purpose of this subsection and as

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	1	further	defined	by	the	department	of	health,	, a	"direct	t	С
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- 2 <u>consumer test" means a diagnostic device that is marketed</u>
- 3 <u>directly to consumers, where the consumer initiates the</u>
- 4 testing process and collects their own human specimen for
- 5 the purpose of testing and analysis by a clinical
- 6 <u>laboratory</u>.

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- 8 **Section 2**. The department of health shall promulgate
- 9 rules and regulations necessary to implement this act on or
- 10 before July 1, 2021.

11

12 Section 3.

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- 14 (a) Except as provided in subsection (b) of this
- 15 section, this act is effective July 1, 2021.

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- 17 (b) Sections 2 and 3 of this act are effective
- 18 immediately upon completion of all acts necessary for a
- 19 bill to become law as provided by Article 4, Section 8 of
- 20 the Wyoming Constitution.

21

22 (END)