

SB3734



103RD GENERAL ASSEMBLY

State of Illinois

2023 and 2024

SB3734

Introduced 2/9/2024, by Sen. Ram Villivalam

SYNOPSIS AS INTRODUCED:

410 ILCS 50/5.3 new

Amends the Medical Patient Rights Act. Requires the Department of Public Health to develop an expanded informed consent document and expanded informed consent process for all patients scheduled to undergo atherectomy.

LRB103 38783 CES 68920 b

A BILL FOR

1 AN ACT concerning health.

2 **Be it enacted by the People of the State of Illinois,**
3 **represented in the General Assembly:**

4 Section 5. The Medical Patient Rights Act is amended by
5 adding Section 5.3 as follows:

6 (410 ILCS 50/5.3 new)

7 Sec. 5.3. Informed consent for patients undergoing
8 atherectomy.

9 (a) By October 1, 2024, the Department of Public Health
10 shall develop an expanded informed consent document and
11 expanded informed consent process for all patients scheduled
12 to undergo atherectomy, which is a procedure that involves
13 opening arteries blocked by plaque using a long, narrow tube
14 with a sharp blade, laser or rotating device on the end to
15 scrape away, dissolve, or break up plaque without making a
16 large incision. The expanded informed consent document and
17 expanded informed consent process shall be completed and shall
18 include, at a minimum, all of the following:

19 (1) all informed consent questions required by federal
20 law, including, but not limited to, questions that
21 address:

22 (A) the nature of the procedure;

23 (B) the risks and benefits of the procedure;

1 (C) reasonable alternatives to the procedure;
2 (D) the risks and benefits of alternative
3 treatment options; and
4 (E) the patient's understanding of the factors
5 described in subparagraphs (A) through (D).
6 (2) a description of the specific risks and outcomes
7 that are associated with atherectomies and that are
8 identified by the National Institutes of Health,
9 including, but not limited to:
10 (A) the impact that smoking has on the patient's
11 risk of repeated claudication;
12 (B) the impact that smoking will have after
13 claudication;
14 (C) the increased risk that occurs when 2 or more
15 arteries are treated, including, but not limited to, a
16 shorter time to repeat claudication, duration between
17 procedures, or an increased likelihood that a repeat
18 atherectomy or another surgical intervention may be
19 needed;
20 (D) common complications that may result from
21 atherectomy, including, but not limited to, the
22 perforation of an artery, and the likelihood of death
23 after these complications;
24 (E) the impact of atherectomy on long-term health,
25 including, but not limited to, the likelihood of a
26 major adverse limb event, amputation, and repeated

1 atherectomies;

2 (F) the increased likelihood of death, amputation,
3 and repeat atherectomies, based on race or ethnicity;
4 and

5 (G) a description of how Black and hispanic
6 patients have a significantly greater risk of death
7 after amputation, if the atherectomy results in a
8 major amputation.

9 (d) The expanded informed consent process shall require:

10 (1) the informed consent document to be first read and
11 completed directly by the patient;

12 (2) after the informed consent document is read and
13 completed by the patient, a health provider to read each
14 line of the informed consent document to the patient and
15 document the patient's answers;

16 (3) the provider to record any discrepancies between
17 the patient's written answers and the patient's verbal
18 answers as documented by the provider;

19 (4) the provider and the patient to sign the document;

20 (5) the provider to provide copies of the informed
21 consent documents to the patient; and

22 (6) the provider to retain and store a copy of the
23 document in medical records.

24 (e) The informed consent document shall minimally include:

25 (1) one column for patient answers and one column for
26 the provider to record the patient's verbal answers; and

1 (2) a space to reconcile discrepancies that exist
2 between the patient's written answers and the patient's
3 verbal answers as documented by the provider.

4 (f) Given the significant risks associated with
5 atherectomies, providers shall ask the patient their preferred
6 or native language and all informed consent documents and
7 verbal questions asked by the provider shall be in the
8 language requested by the patient.