J3 5lr0174

By: Chairman, Health and Government Operations Committee (By Request - Departmental - Health and Mental Hygiene) Introduced and read first time: February 11, 2005 Assigned to: Health and Government Operations

30 BY repealing31 Article - Health - General

A BILL ENTITLED

1	AN ACT concerning
2	Health Care Facilities and Laboratories - Accreditation Organizations and Deeming
4 5 6 7 8 9 10 12 13 14 15 16 17 18 20 21 22	deemed status to certain health care facilities; requiring certain accreditation organizations to apply to the Secretary for approval; requiring the Secretary to take certain actions before allowing an accreditation organization to conduct inspections or surveys on behalf of the Department; requiring the Department to establish a certain agreement with the accreditation organization; requiring disclosure to the public of certain reports by approved accreditation organizations; authorizing the Department to conduct certain inspections; authorizing the Secretary to withdraw approval from an accreditation organization or deemed status from a health care facility under certain circumstances; repealing and altering certain provisions of law relating to accreditation and deemed status of certain health care facilities; defining
23	
24 25 26 27 28	Section 17-202, 19-308, 19-309(b), 19-319(c), 19-323(a), 19-3B-03(d), 19-404, 19-1204, and 19-1207 Annotated Code of Maryland

1 2 3	Section 19-705.1(g)(5) and 19-1805(b) Annotated Code of Maryland (2000 Replacement Volume and 2004 Supplement)						
4 5 6 7 8 9	BY adding to Article - Health - General Section 19-2101 and 19-2102, to be under the new subtitle "Subtitle 21. Accreditation of Health Care Facilities" Annotated Code of Maryland (2000 Replacement Volume and 2004 Supplement)						
10 11	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:						
12	Article - Health - General						
13	17-202.						
14 15	(a) (1) The Secretary shall adopt regulations that set standards and requirements for medical laboratories.						
	(2) The regulations shall contain the standards and requirements that the Secretary considers necessary to assure the citizens of this State that medical laboratories provide safe and reliable services.						
19 20	(b) To assure compliance with the standards and requirements adopted in regulations pursuant to this subtitle, the Secretary shall:						
21 22	(1) Conduct an inspection of each medical laboratory for which a license to operate is sought; and						
23 24	(2) Conduct an inspection periodically of each medical laboratory for which a license has been issued.						
25 26	[(c) (1) A medical laboratory accredited by an organization approved by the Secretary shall be deemed to meet the:						
27 28	(i) State's inspection requirements under subsection (b)(2) of this section; or						
	(ii) State's standards under this subtitle if the Secretary determines the standards of the accrediting organization equivalent to the State's requirements.						
32 33	(2) The medical laboratory shall submit the report of the accrediting organization to the Secretary within 30 days of its receipt.						

		rpose of	etary may inspect a medical laboratory accredited by an a complaint investigation or to validate findings of the
	this section, the Secreta	ary shall	In addition to the regulations adopted under subsection (a) of adopt regulations establishing specific standards for cytology, including regulations that:
7	((i)	Limit the number of slides an individual may examine;
8 9			Require that the examination of cytology slides be performed in license issued by the Secretary;
10 11	cytology specimens or		Prohibit payment to cytotechnologists for the examination of n a piecework basis;
12 13	of all negative gynecol		Require cytology laboratories to review no less than 10 percent lides;
14 15			Require that the cytology review be performed by an individual cytotechnologist or a pathologist;
	,		Require the individual who directs the laboratory to establish lity assurance program using standards acceptable to
21	specimens, make appro	opriate co	Require cytology laboratories to reject unsatisfactorily prepared omments regarding the quality of the specimen, and corily prepared specimens for 5 years subject to review
23 24			Require cytology laboratories to maintain and store for 5 years ny slide that was examined;
25	((ix)	Require all cytology reports to be retained for at least 10 years;
26 27			Prohibit any person from sending cytology specimens to a te laboratories, not licensed by the Department;
		in this S	Require all individuals who examine gynecological slides tate to demonstrate satisfactory performance in an testing program; and
			Establish any additional standards the Secretary considers all laboratories engaged in cytology provide safe and
	to any other relevant p	rovision	irements of paragraph (1) of this subsection are in addition of this subtitle or relevant regulation adopted in vision of this subtitle governing medical laboratories.

3		n, the Secretary shall adopt regulations to establish and conduct vesting program for all cytology personnel that examine
	(2) testing program shall Mental Hygiene who	All cytology proficiency tests under the State cytology proficiency be conducted by an employee of the Department of Health and shall:
8		(i) Hand carry all testing materials to the testing site; and
9		(ii) Directly supervise the on-site proficiency testing.
	the Secretary to cove program under this se	A medical laboratory shall pay the Department a fee established by r the cost of the laboratory's State cytology proficiency testing ection.
13 14	(4) testing program that:	The Secretary shall adopt regulations for the cytology proficiency
15 16	and	(i) Define satisfactory cytology proficiency testing performance;
17 18	testing program must	(ii) Set standards and requirements that a cytology proficiency meet before it can be designated an approved program.
	(5) proficiency testing profit of this subtitle.	The Secretary may accept the testing results of an approved cytology rogram as meeting the cytology proficiency testing requirement
22	19-308.	
	standards of services	retary shall adopt reasonable rules and regulations that set for related institutions, nonaccredited hospitals, and ntial treatment centers in the following areas:
26	(1)	The care of patients;
27	(2)	The medical supervision of patients;
28	(3)	The physical environment;
29	(4)	Disease control;
30	(5)	Sanitation;
31	(6)	Safety; and
32	(7)	Dietary matters.

2	(b) (1) To assure compliance with the standards adopted under this subtitle, he Secretary shall have an inspection made:	
	(i) Of each related institution, each ACCREDITED HOSPITAL Oronaccredited hospital, and each ACCREDITED RESIDENTIAL TREATMENT CENTER OR nonaccredited residential treatment center for which a license is sought; and	R
8	(ii) Periodically of each related institution, each ACCREDITED HOSPITAL OR nonaccredited hospital, and each ACCREDITED RESIDENTIAL TREATMENT CENTER OR nonaccredited residential treatment center for which a icense has been issued.	
10 11	[(2) An accredited hospital and an accredited residential treatment center shall be subject to inspections under this subtitle by the Department to:	
12 13	(i) Investigate a complaint in accordance with § 19-309 of this part;	
16 17 18 19	(ii) Review compliance with a written progress report or other documentation of corrective action in response to a focused survey submitted by the hospital or residential treatment center to the Joint Commission on Accreditation of Healthcare Organizations in response to a Type I finding that the hospital or residential treatment center is only in partial compliance with the patient care standards established by the Joint Commission on Accreditation of Healthcare Organizations; or	
23	(iii) Monitor corrective action, in accordance with § 19-360 of this subtitle, for any serious or life-threatening patient care deficiency identified by the Joint Commission on Accreditation of Healthcare Organizations, the Health Care Financing Administration, or the Department.	
27	(3) In addition to other provisions of this subsection, an accredited hospital shall be subject to inspections under this subtitle by the Department for reviewing compliance with licensure requirements for risk management, utilization review, and physician credentialing under § 19-319 of this subtitle.	
31	(4) When conducting an inspection of an accredited hospital or accredited residential treatment center, the Department shall use the current applicable standards of the Joint Commission on Accreditation of Healthcare Organizations.]	
33 34	[(5)] (2) At least 2 inspections a year of each related institution shall be unannounced.	
37	[(6)] (3) The part of a building that contains part of a hospital, residential treatment center, or related institution and any outbuilding are considered part of the facility and are subject to inspection to determine occupancy status for licensing purposes.	

	[(7)] (4) Subject to § 2-1246 of the State Government Article, during each regular session of the General Assembly, the Department shall submit to the General Assembly a report on the inspections.
	[(8)] (5) (i) An employee of the Department may not inform a hospital, residential treatment center, or related institution of any proposed inspection activity, unless the chief of the employee's division directs the employee to do so.
	(ii) An employee who violates any provision of this paragraph is guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$1,000 or imprisonment not exceeding 1 year or both.
12	[(c) (1) An accredited hospital or accredited residential treatment center shall submit the survey findings of the Joint Commission on Accreditation of Healthcare Organizations within 30 days of receipt by the hospital or the residential treatment center to the Department.
16 17	(2) Except as provided in paragraph (5) of this subsection, an accredited hospital's or accredited residential treatment center's official accreditation report and any summary of the report, written progress reports, or plans of correction which are submitted to the Secretary are confidential and are not discoverable or admissible as evidence in any civil action.
21	(3) The Secretary shall refer any request for public inspection of a survey report made by the Joint Commission on Accreditation of Healthcare Organizations for an accredited hospital or accredited residential treatment center directly to the hospital or residential treatment center.
25 26 27	(4) Upon the written request of any person, within 15 working days, the accredited hospital or accredited residential treatment center shall make available for public inspection the most recent accreditation letter and any Type I recommendations if the Joint Commission on Accreditation of Healthcare Organizations has made a final decision on any appeal by the hospital or residential treatment center of the Type I recommendations.
	(5) If information is released in accordance with paragraph (4) of this subsection, that information is no longer confidential, but is not discoverable or admissible in any civil action.
34	(6) An accreditation report, including any summary of the report and any information contained in the report, disclosed by a hospital or residential treatment center, the Joint Commission on the Accreditation of Healthcare Organizations, or the Department is not admissible or discoverable in any civil action.
	(7) If an accredited hospital or accredited residential treatment center willfully fails to comply with the provisions of this subsection, the Secretary may impose a penalty not to exceed \$1,000 a day for each day the violation continues.]

1	19-309.		
	(b) (1) nonlife-threatening de the hospital or resider	eficiency,	ve expeditiously a complaint that alleges the existence of any the Department may refer the complaint directly to ment center.
7		of a health	priate, issues relating to the practice of medicine or the a professional shall be referred to the hospital or the l may be referred to the appropriate licensure board
11 12	complaint alleges the	not satisfa existence ent invest	epartment determines that the hospital or residential actorily addressed the referred complaint or where the e of a life-threatening deficiency, the Department shall igation. [When conducting its independent shall use:
			For an accredited hospital or accredited residential treatment tandards of review of the Joint Commission on rganizations;
17 18		(ii) standards	For a nonaccredited hospital or nonaccredited residential adopted by the Secretary under this subtitle;
			For an accredited or nonaccredited hospital that is a facility as is subtitle, the requirements of §§ 10-701 through
22 23			For an accredited or nonaccredited residential treatment center, through 10-709 of this article.]
24	19-319.		
	` ' ' ' '	, for the h	licant shall have a certificate of need, as required under assistant, residential treatment center, or related
28 29	(2) operated shall[:	The hosp	pital, residential treatment center, or related institution to be
30 31	center; or	(i)	Be an accredited hospital or accredited residential treatment
32 33	this subtitle and Subt	(ii) itle 12 of	Meet] MEET the requirements that the Secretary adopts under this title.
34	19-323.		
35 36			as provided under [paragraphs (2) and (3)] PARAGRAPH (2) of related institution, AN ACCREDITED HOSPITAL, or a

	nonaccredited hospital expires on the first anniversary of its effective date, unless the license is renewed for a 1-year term as provided in this section.				
3	[(2) accreditation expire		se for an accredited hospital expires when the certificate of		
5 6	[(3)] defined under Subtit	(2) tle 18 of th	A license for a nursing facility and an assisted living program as is title shall be for a 2-year term.		
7	19-3B-03.				
8 9	(d) [(1) approved by the Sec		anding ambulatory care facility accredited by an organization ll be deemed to meet State licensing requirements.		
10 11	` '	(i) itation org	The freestanding ambulatory care facility shall submit the anization to the Secretary within 30 days of its receipt.		
12 13	for public inspectio	(ii) n.	All reports submitted under this paragraph shall be available		
14	(3)	The Sec	cretary may:		
15 16	of a complaint inve	(i) stigation;	Inspect a freestanding ambulatory care facility for the purpose		
17 18		(ii) entified in	Inspect a freestanding ambulatory care facility to follow up on a an accreditation report; and		
19 20	accreditation report	(iii)	Annually conduct a survey to validate the findings of		
	\ /-	y under [p	eretary may delegate to the Kidney Disease Commission the aragraph (3) of this subsection] § 19-3B-07 OF THIS dialysis centers.		
24	19-404.				
			shall adopt rules and regulations that set standards for fety, welfare, and comfort of patients of home health		
		l license re	gulations shall provide for the licensing of home health enewal, and shall establish standards that require as a h agencies:		
	record all reasonable	le efforts to	10 days of acceptance of a patient for skilled care, make and contact a physician to obtain the signed order required 2) OF THIS SUBSECTION;		
34 35	` '		cept patients for skilled care do so only on the signed order of 8 days after acceptance;		

9

30

(i)

A physician;

1		(ii)	A registered nurse; or
2 3	advanced training to s	(iii) supervise	Another health professional who is qualified sufficiently by the same kind of services in a hospital; and
4 5	(6) utilization statistics.	Require	submission of an annual report which includes service
6 7	[(d) (1) Secretary shall be dee		health agency accredited by an organization approved by the neet State licensing regulations.
8 9	(2) accreditation organiza	(i) ation to th	The home health agency shall submit the report of the se Secretary within 30 days of its receipt.
10 11	for public inspection.	(ii)	All reports submitted under this paragraph shall be available
12	(3)	The Sec	retary may:
13 14	investigation;	(i)	Inspect the home health agency for the purpose of a complaint
15 16	problem identified in	(ii) an accree	Inspect the home health agency to follow up on a serious ditation organization's report; and
		(iii) to validat	Annually, conduct a survey of up to 5 percent of all home health te the findings of an accreditation organization's
20 21	[(e)] (D) home health agency t		visions of this section do not waive the requirement for a a certificate of need.
22	19-705.1.		
	(2)	(i) ion as me	The Secretary may accept all or part of a report of an approved seting the external review requirements under this
28	report of an approved	l accredit	Except as provided in subparagraph (iii) of this paragraph, a ing organization used by the Department as meeting into under this subtitle shall be made available to the
32		l accredit	The Department may not disclose and shall treat as immercial and financial information contained in a ing organization in accordance with § 10-617(d) of the
34 35	organization to:	(iv)	The Department may inspect a facility of a health maintenance

1 2	established under this subtitle	1.	Determine compliance with any quality requirement
3	accrediting organization; or	2.	Follow up on a serious problem identified by an approved
5		3.	Investigate a complaint.]
6	19-1204.		
7	[(a)] A comprehensi	ve rehabil	itation facility shall[:
			nabilitation programs that have been accredited by sion on Accreditation of Rehabilitation
	* *	cretary an	ommission on Accreditation of Rehabilitation by information obtained by the Commission on ies during:
14	(i)	The acc	creditation process; and
15	(ii)	Any ins	spection; and
16	(3) Meet a	any other s	standard that the Secretary may adopt by regulation.
19 20	the Commission on Accredit subsection (a) of this section	ation of R for any re	e rehabilitation facility to achieve accreditation by the chabilitation Facilities as required by chabilitation program that the facility provides, tion requirement for the facility for no more
22	(1) July 1.	1986; or	
23 24			ch the facility begins operation] MEET ANY RY ADOPTS BY REGULATION.
25	19-1207.		
			mself out as providing a complete array of on provides comprehensive physical
29 30	(b) A health care fa specialized rehabilitation pro		not provide or hold itself out as providing any ess[:
			s been accredited by the Commission on ies to provide the particular specialized

3	Accreditation of Rehabilitation Facilities under § 19-1204(b) of this subtitle to provide the particular specialized rehabilitation program] THE FACILITY IS LICENSED BY THE DEPARTMENT.					
5 6	(c) unless the pe			t provide comprehensive physical rehabilitation services quirements of this subtitle.		
7	19-1805.					
				The Secretary may accept all or part of a report of an approved eting the State licensing requirements for renewal of a iving facility program.		
				The Secretary may not accept all or part of a report of an attion as meeting the State licensing requirements for an sisted living facility program.		
	an accredition by the assist			The assisted living facility program shall submit the report of the Secretary within 30 days of the receipt of the report program.		
19				The report of an accrediting organization used by the ate licensing requirements for renewal of a license to ity program shall be made available to the public on		
21		(3)	The Sec	retary may inspect an assisted living facility program to:		
22			(i)	Investigate a complaint;		
23 24	accrediting	organizat	(ii) ion; or	Follow up on a serious problem identified by an approved		
25			(iii)	Validate findings of an approved accrediting organization.]		
26				SUBTITLE 21. ACCREDITATION OF HEALTH CARE FACILITIES.		
27	19-2101.					
	(A) INDICATE		S SUBTI	TLE THE FOLLOWING WORDS HAVE THE MEANINGS		
	CONDUCT	S INSPE	CTIONS	ION ORGANIZATION" MEANS A PRIVATE ENTITY THAT AND SURVEYS OF HEALTH CARE FACILITIES BASED ON ED AND DEVELOPED STANDARDS.		
	` /	MAY BE		TUS" MEANS A STATUS UNDER WHICH A HEALTH CARE PT FROM ROUTINE SURVEYS CONDUCTED BY THE		

1 (D) "HEALTH CARE FACILITY" MEANS: 2 A HOSPITAL AS DEFINED IN § 19-301(B) OF THIS TITLE; (1) (2) A HEALTH MAINTENANCE ORGANIZATION AS DEFINED IN § 19-701(G) 4 OF THIS ARTICLE; A FREESTANDING AMBULATORY CARE FACILITY AS DEFINED § IN (3) 6 19-3B-01 OF THIS TITLE; (4) AN ASSISTED LIVING FACILITY AS DEFINED IN § 19-1801 OF THIS 8 TITLE; 9 (5) A LABORATORY AS DEFINED IN § 17-201 OF THIS ARTICLE; 10 (6) A HOME HEALTH AGENCY AS DEFINED IN § 19-401 OF THIS TITLE; 11 AND A RESIDENTIAL TREATMENT CENTER AS DEFINED IN § 19-301 OF 12 (7) 13 THIS TITLE. 14 19-2102. ACCREDITATION ORGANIZATIONS SHALL APPLY TO THE SECRETARY FOR (A) 16 APPROVAL. 17 (B) PRIOR TO APPROVAL OF AN ACCREDITATION ORGANIZATION, THE 18 SECRETARY SHALL: 19 (1)DETERMINE THAT THE STANDARDS OF THE ACCREDITATION 20 ORGANIZATION ARE EQUAL TO OR MORE STRINGENT THAN EXISTING STATE 21 REQUIREMENTS: 2.2. EVALUATE THE SURVEY OR INSPECTION PROCESS OF THE (2) 23 ACCREDITATION ORGANIZATION TO ENSURE THE INTEGRITY OF THE SURVEY 24 PROCESS; AND ENTER INTO A FORMAL WRITTEN AGREEMENT WITH THE 26 ACCREDITATION ORGANIZATION THAT INCLUDES REQUIREMENTS FOR: 27 NOTICE OF ALL SURVEYS AND INSPECTIONS; (I) 28 (II)SHARING OF COMPLAINTS AND OTHER RELEVANT 29 INFORMATION; 30 PARTICIPATION OF THE DEPARTMENT IN ACCREDITATION (III)

ANY OTHER PROVISION NECESSARY TO ENSURE THE

31 ORGANIZATION ACTIVITIES; AND

(IV)

33 INTEGRITY OF THE ACCREDITATION AND LICENSURE PROCESS.

- 1 (C) (1) WHEN AN APPROVED ACCREDITATION ORGANIZATION HAS ISSUED A
- 2 FINAL REPORT FINDING A HEALTH CARE FACILITY TO BE IN SUBSTANTIAL
- 3 COMPLIANCE WITH THE ACCREDITATION ORGANIZATION'S STANDARDS, THE
- 4 DEPARTMENT SHALL ACCEPT THE REPORT AS EVIDENCE THAT THE HEALTH CARE
- 5 FACILITY HAS MET STATE LICENSURE REQUIREMENTS AND SHALL GRANT THE
- 6 HEALTH CARE FACILITY DEEMED STATUS.
- 7 (2) A HEALTH CARE FACILITY THAT FAILS TO ACHIEVE SUBSTANTIAL
- 8 COMPLIANCE WITH THE STANDARDS OF AN APPROVED ACCREDITATION
- 9 ORGANIZATION MAY BE SUBJECT TO THE PROVISIONS OF § 19-360 OF THIS TITLE.
- 10 (D) (1) AN APPROVED ACCREDITATION ORGANIZATION SHALL SEND THE
- 11 DEPARTMENT ANY PRELIMINARY AND FINAL REPORT OF EACH INSPECTION AND
- 12 SURVEY AT THE TIME IT IS SENT TO THE HEALTH CARE FACILITY.
- 13 (2) A FINAL REPORT OF AN APPROVED ACCREDITATION ORGANIZATION
- 14 SHALL BE MADE IMMEDIATELY AVAILABLE TO THE PUBLIC ON REQUEST.
- 15 (3) A PRELIMINARY OR FINAL REPORT OF AN APPROVED
- 16 ACCREDITATION ORGANIZATION IS NOT ADMISSIBLE IN EVIDENCE IN ANY CIVIL
- 17 ACTION OR PROCEEDING.
- 18 (E) THE DEPARTMENT MAY INSPECT AN ACCREDITED HEALTH CARE
- 19 FACILITY TO:
- 20 (1) DETERMINE COMPLIANCE WITH ANY QUALITY REQUIREMENT;
- 21 (2) FOLLOW UP ON ANY SERIOUS PROBLEM IDENTIFIED BY AN
- 22 APPROVED ACCREDITATION ORGANIZATION;
- 23 (3) INVESTIGATE A COMPLAINT;
- 24 (4) PARTICIPATE IN OR OBSERVE A SURVEY OF AN APPROVED
- 25 ACCREDITATION ORGANIZATION; OR
- 26 (5) VALIDATE THE FINDINGS OF AN APPROVED ACCREDITATION
- 27 ORGANIZATION.
- 28 (F) ON A DETERMINATION BY THE SECRETARY THAT AN APPROVED
- 29 ACCREDITATION ORGANIZATION HAS FAILED TO MEET ITS OBLIGATIONS UNDER
- 30 THIS SECTION, THE SECRETARY MAY WITHDRAW:
- 31 (1) THE APPROVAL FROM THE ACCREDITATION ORGANIZATION; AND
- 32 (2) THE DEEMED STATUS GIVEN TO A HEALTH CARE FACILITY BY THE
- 33 ACCREDITED ORGANIZATION.
- 34 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
- 35 effect October 1, 2005.