J3 6lr0028

HB 1320/05 - HGO

By: Chairman, Finance Committee (By Request - Departmental - Health and Mental Hygiene) Introduced and read first time: January 16, 2006

Rules suspended Assigned to: Finance

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 20 21 22 23	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 certain terms; making a stylistic change; and generally relating to accreditation
24 25 26 27 28 29	Section 17-202, 19-308, 19-309(b), 19-319(c), 19-323(a), 19-3B-03(d), 19-404, 19-1204, 19-1207, and 19-1805 Annotated Code of Maryland

30 BY repealing

31 Article - Health - General

1 2 3	Section 19-705.1(g)(5) Annotated Code of Maryland (2005 Replacement Volume and 2005 Supplement)
4 5 6 7 8 9	BY adding to Article - Health - General Section 19-2301 and 19-2302 to be under the new subtitle "Subtitle 23. Accreditation of Health Care Facilities" Annotated Code of Maryland (2005 Replacement Volume and 2005 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.

	(3) The Secretary may inspect a medical laboratory accredited by an organization for the purpose of a complaint investigation or to validate findings of the accrediting organization.]						
	[(d)] (C) (1) In addition to the regulations adopted under subsection (a) of this section, the Secretary shall adopt regulations establishing specific standards for medical laboratories engaged in cytology, including regulations that:						
7		(i)	Limit the number of slides an individual may examine;				
8 9	a medical laboratory t		Require that the examination of cytology slides be performed in license issued by the Secretary;				
10 11	cytology specimens of		Prohibit payment to cytotechnologists for the examination of on a piecework basis;				
12 13	of all negative gynec		Require cytology laboratories to review no less than 10 percent lides;				
14 15	who qualifies as a su		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			Require cytology laboratories to reject unsatisfactorily prepared comments regarding the quality of the specimen, and torily prepared specimens for 5 years subject to review				
23 24	from the date of exar	(viii) nination a	Require cytology laboratories to maintain and store for 5 years my slide that was examined;				
25		(ix)	Require all cytology reports to be retained for at least 10 years;				
26 27	laboratory, including	(x) out-of-sta	Prohibit any person from sending cytology specimens to a ate laboratories, not licensed by the Department;				
	acquired from person approved cytology pr		Require all individuals who examine gynecological slides State to demonstrate satisfactory performance in an testing program; and				
	necessary to assure the reliable services.	(xii) nat medica	Establish any additional standards the Secretary considers al laboratories engaged in cytology provide safe and				
		provision	direments 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.

1 2	(b) (1) To assure compliance with the standards adopted under this subtitle, the Secretary shall have an inspection made:						
			Of each related institution, each ACCREDITED HOSPITAL OR th ACCREDITED RESIDENTIAL TREATMENT CENTER reatment center for which a license is sought; and				
8		ER OR n	Periodically of each related institution, each ACCREDITED hospital, and each ACCREDITED RESIDENTIAL conaccredited residential treatment center for which a				
10 11	/		edited hospital and an accredited residential treatment center under this subtitle by the Department to:				
12 13	part;	(i)	Investigate a complaint in accordance with § 19-309 of this				
16 17 18 19	documentation of cor hospital or residential Healthcare Organizat residential treatment	treatmer ions in re center is	Review compliance with a written progress report or other ction in response to a focused survey submitted by the at center to the Joint Commission on Accreditation of sponse to a Type I finding that the hospital or only in partial compliance with the patient care wint Commission on Accreditation of Healthcare				
23	Joint Commission on	Accredit	Monitor corrective action, in accordance with § 19-360 of this threatening patient care deficiency identified by the ation of Healthcare Organizations, Centers for tes, or the Department.				
27	hospital shall be subjective reviewing compliance	ect to insp with lice	on to other provisions of this subsection, an accredited pections under this subtitle by the Department for ensure requirements for risk management, utilization aling under § 19-319 of this subtitle.				
31	accredited residential	treatmen	onducting an inspection of an accredited hospital or at center, the Department shall use the current ont Commission on Accreditation of Healthcare				
33 34	[(5)] unannounced.	(2)	At least 2 inspections a year of each related institution shall be				
37		facility a	The part of a building that contains part of a hospital, related institution and any outbuilding are and are subject to inspection to determine occupancy				

	[(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.						
		To resolve expeditiously a complaint that alleges the existence of any ciency, the Department may refer the complaint directly to all treatment center.					
7	licensure or conduct of	f appropriate, issues relating to the practice of medicine or the a health professional shall be referred to the hospital or the nter and may be referred to the appropriate licensure board					
11 12	(3) If the Department determines that the hospital or residential treatment center has not satisfactorily addressed the referred complaint or where the complaint alleges the existence of a life-threatening deficiency, the Department shall conduct an independent investigation. [When conducting its independent investigation, the Department shall use:						
		For an accredited hospital or accredited residential treatment icable standards of review of the Joint Commission on icare Organizations;					
17 18		i) For a nonaccredited hospital or nonaccredited residential andards adopted by the Secretary under this subtitle;					
		For an accredited or nonaccredited hospital that is a facility as 2.2 of this subtitle, the requirements of §§ 10-701 through nd					
22 23	(iv) For an accredited or nonaccredited residential treatment center, 8 the requirements of §§ 10-701 through 10-709 of this article.]						
24	19-319.						
		The applicant shall have a certificate of need, as required under for the hospital, residential treatment center, or related ed.					
28 29	operated shall[:	The hospital, residential treatment center, or related institution to be					
30 31	center; or	Be an accredited hospital or accredited residential treatment					
32 33	this subtitle and Subtit	i) Meet] MEET the requirements that the Secretary adopts under e 12 of this title.					
34	19-323.						
35 36		except as provided under [paragraphs (2) and (3)] PARAGRAPH (2) of the for a related institution, AN ACCREDITED HOSPITAL, or a					

1 nonaccredited hospital expires on the first anniversary of its effective date, unless the

2	license is renewed for a 1-year term as provided in this section.						
3	[(2) A license for an accredited hospital expires when the certificate of accreditation expires.						
5 6	(3)] (2) A license for a nursing facility and an assisted living program as defined under Subtitle 18 of this title shall be for a 2-year term.						
7	19-3B-03.						
8 9	(d) [(1) A freestanding ambulatory care facility accredited by an organization approved by the Secretary shall be deemed to meet State licensing requirements.						
10 11	(2) (i) The freestanding ambulatory care facility shall submit the report of the accreditation organization to the Secretary within 30 days of its receipt.						
12 13	(ii) All reports submitted under this paragraph shall be available for public inspection.						
14	(3) The Secretary may:						
15 16	(i) Inspect a freestanding ambulatory care facility for the purpose of a complaint investigation;						
17 18	(ii) Inspect a freestanding ambulatory care facility to follow up on a serious problem identified in an accreditation report; and						
19 20	(iii) Annually conduct a survey to validate the findings of accreditation reports.						
	(4)] The Secretary may delegate to the Kidney Disease Commission the Secretary's authority under [paragraph (3) of this subsection] § 19-3B-07 OF THIS SUBTITLE to inspect kidney dialysis centers.						
24	19-404.						
	(a) The Department shall adopt rules and regulations that set standards for the care, treatment, health, safety, welfare, and comfort of patients of home health agencies.						
	(b) The rules and regulations shall provide for the licensing of home health agencies and annual license renewal, and shall establish standards that require as a minimum, that all home health agencies:						
	(1) Within 10 days of acceptance of a patient for skilled care, make and record all reasonable efforts to contact a physician to obtain the signed order required under [paragraph (2)] ITEM (2) OF THIS SUBSECTION;						
34 35	(2) That accept patients for skilled care do so only on the signed order of a physician obtained within 28 days after acceptance;						

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30

(i)

A physician;

- 29 public on request.
- 30 (iii) The Department may not disclose and shall treat as
- 31 confidential all confidential commercial and financial information contained in a
- report of an approved accrediting organization in accordance with § 10-617(d) of the
- State Government Article.
- The Department may inspect a facility of a health maintenance 34 (iv)
- 35 organization to:

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 comprehensiv	e rehabili	tation facility shall[:				
	(1) Provide only rehabilitation programs that have been accredited by and meet the standards of the Commission on Accreditation of Rehabilitation) Facilities;						
	` '	retary an	ommission on Accreditation of Rehabilitation y information obtained by the Commission on es during:				
14	(i)	The acc	reditation process; and				
15	(ii)	Any ins	pection; and				
16	(3) Meet an	ny other s	tandard that the Secretary may adopt by regulation.				
19 20	7 (b) To allow a comprehensive rehabilitation facility to achieve accreditation by 8 the Commission on Accreditation of Rehabilitation Facilities as required by 9 subsection (a) of this section for any rehabilitation program that the facility provides, 0 the Secretary may waive the accreditation requirement for the facility for no more 1 than 2 years from:						
22	(1) July 1,	1986; or					
23 24			th the facility begins operation] MEET ANY RY ADOPTS BY REGULATION.				
25	19-1207.						
			mself out as providing a complete array of n provides comprehensive physical				
29 30	(b) A health care factor specialized rehabilitation programmes.		not provide or hold itself out as providing any ss[:				
	` '	_	been accredited by the Commission on es to provide the particular specialized				

3	(2) The facility is applying for accreditation from the Commission on 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) A person may not provide comprehensive physical rehabilitation services unless the person meets the requirements of this subtitle.							
7	19-1805.							
8	(a) T	The Departi	nent shall:					
9 10	provided;	1) De	ine different levels of assisted living according to the level of care					
11 12	according to the		uire all assisted living programs to be licensed to operate he program;					
15	(3) Develop a waiver process for authorizing an assisted living program to continue to care for an individual whose medical or functional condition has changed since admission to the program to an extent that the level of care required by the individual exceeds the level of care for which the program is licensed;							
17 18	(4) Promote affordable and accessible assisted living programs throughout the State;							
19	(:	5) Est	ablish and enforce quality standards for assisted living programs;					
20 21	(6) Require periodic inspections of assisted living program facilities, including at least an annual unannounced on-site inspection;							
22 23	2 (7) Establish requirements for the qualifications or training or both of assisted living program employees;							
24 25	Establish a "resident bill of rights" for residents of assisted living program facilities; and							
26 27	Define which, if any, assisted living programs may be exempt from the requirements of § 19-311 of this title.							
	accrediting org		The Secretary may accept all or part of a report of an approved as meeting the State licensing requirements for renewal of a ted living facility program.					
	approved accr		The Secretary may not accept all or part of a report of an inization as meeting the State licensing requirements for an in assisted living facility program.					
			The assisted living facility program shall submit the report of in to the Secretary within 30 days of the receipt of the report lity program.					

3	(ii) The report of an accrediting organization used by the Department as meeting the State licensing requirements for renewal of a license to operate an assisted living facility program shall be made available to the public on request.								
5	(3)	(3) The Secretary may inspect an assisted living facility program to:							
6		(i)	Investiga	Investigate a complaint;					
7 8	7 (ii) Follow up on a serious problem identified by an approved accrediting organization; or							proved	
9		(iii)	Validate	findings	of an approv	ed accredit	ing organiz	zation.]	
12	[(c)] (B) (1) The Department, in consultation with representatives of the affected industry and advocates for residents of the facilities and with the approval of the Department of Aging and the Department of Human Resources, shall adopt regulations to implement this subtitle.								
14	The regulations adopted under paragraph (1) of this subsection shall:							on shall:	
15 16	5 (i) Provide for the licensing of assisted living programs and the 6 renewal of licenses;								
19	Require the Secretary to charge fees in a manner that will produce funds not to exceed the actual direct and indirect costs to the Department for inspecting assisted living program facilities and maintaining the licensure program for assisted living programs under this subtitle;								
23	1 (iii) Require the Department, during a survey or other inspection of 2 an assisted living program, to review the number of waivers granted to the program 3 under subsection (a)(3) of this section and determine whether a change in the 4 program's licensure status is warranted; and								
	conspicuous place vis interested parties:				ed living prog residents of			ı a	
28 29	survey;		1.	A.	Its statement	t of deficie	ncies for th	e most recent	
30 31	federal, State, or local	surveyo	B. rs; and	Any sub	sequent com	plaint inves	tigations c	onducted by	
32 33	or complaint investiga	ation; or	C.	Any plan	ns of correcti	on in effect	with respe	ect to the surve	
34 35	listed in item 1 of this	item.	2.	A notice	of the location	on, within t	he facility,	of the items	

1 SUBTITLE 23. ACCREDITATION OF HEALTH CARE FACILITIES.

- 2 19-2301.
- $3\ \ \,$ (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 4 INDICATED.
- 5 (B) "ACCREDITATION ORGANIZATION" MEANS A PRIVATE ENTITY THAT
- 6 CONDUCTS INSPECTIONS AND SURVEYS OF HEALTH CARE FACILITIES BASED ON
- 7 NATIONALLY RECOGNIZED AND DEVELOPED STANDARDS.
- 8 (C) "DEEMED STATUS" MEANS A STATUS UNDER WHICH A HEALTH CARE
- 9 FACILITY MAY BE EXEMPT FROM ROUTINE SURVEYS CONDUCTED BY THE
- 10 DEPARTMENT.
- 11 (D) "HEALTH CARE FACILITY" MEANS:
- 12 (1) A HOSPITAL AS DEFINED IN § 19-301(B) OF THIS TITLE;
- 13 (2) A HEALTH MAINTENANCE ORGANIZATION AS DEFINED IN § 19-701(G)
- 14 OF THIS TITLE;
- 15 (3) A FREESTANDING AMBULATORY CARE FACILITY AS DEFINED IN §
- 16 19-3B-01 OF THIS TITLE;
- 17 (4) AN ASSISTED LIVING FACILITY AS DEFINED IN § 19-1801 OF THIS
- 18 TITLE;
- 19 (5) A LABORATORY AS DEFINED IN § 17-201 OF THIS ARTICLE;
- 20 (6) A HOME HEALTH AGENCY AS DEFINED IN § 19-401 OF THIS TITLE;
- 21 (7) A RESIDENTIAL TREATMENT CENTER AS DEFINED IN § 19-301 OF
- 22 THIS TITLE; AND
- 23 (8) A COMPREHENSIVE REHABILITATION FACILITY AS DEFINED IN §
- 24 19-1201 OF THIS TITLE.
- 25 19-2302.
- 26 (A) ACCREDITATION ORGANIZATIONS SHALL APPLY TO THE SECRETARY FOR
- 27 APPROVAL.
- 28 (B) PRIOR TO APPROVAL OF AN ACCREDITATION ORGANIZATION, THE
- 29 SECRETARY SHALL:
- 30 (1) DETERMINE THAT THE STANDARDS OF THE ACCREDITATION
- 31 ORGANIZATION ARE EQUAL TO OR MORE STRINGENT THAN EXISTING STATE
- 32 REQUIREMENTS;

- 15 **UNOFFICIAL COPY OF SENATE BILL 102** EVALUATE THE SURVEY OR INSPECTION PROCESS OF THE 1 2 ACCREDITATION ORGANIZATION TO ENSURE THE INTEGRITY OF THE SURVEY 3 PROCESS; AND ENTER INTO A FORMAL WRITTEN AGREEMENT WITH THE (3) 5 ACCREDITATION ORGANIZATION THAT INCLUDES REQUIREMENTS FOR: NOTICE OF ALL SURVEYS AND INSPECTIONS; 6 (I) 7 (II)SHARING OF COMPLAINTS AND OTHER RELEVANT 8 INFORMATION; (III)PARTICIPATION OF THE DEPARTMENT IN ACCREDITATION 10 ORGANIZATION ACTIVITIES; AND (IV) ANY OTHER PROVISION NECESSARY TO ENSURE THE 12 INTEGRITY OF THE ACCREDITATION AND LICENSURE PROCESS. WHEN AN APPROVED ACCREDITATION ORGANIZATION HAS ISSUED A 13 (C) (1) 14 FINAL REPORT FINDING A HEALTH CARE FACILITY TO BE IN SUBSTANTIAL 15 COMPLIANCE WITH THE ACCREDITATION ORGANIZATION'S STANDARDS, THE 16 DEPARTMENT SHALL ACCEPT THE REPORT AS EVIDENCE THAT THE HEALTH CARE 17 FACILITY HAS MET STATE LICENSURE REQUIREMENTS AND SHALL GRANT THE 18 HEALTH CARE FACILITY DEEMED STATUS. A HEALTH CARE FACILITY THAT FAILS TO ACHIEVE SUBSTANTIAL 19 20 COMPLIANCE WITH THE STANDARDS OF AN APPROVED ACCREDITATION 21 ORGANIZATION MAY BE SUBJECT TO THE PROVISIONS OF § 19-360 OF THIS TITLE. 22 (D) (1)AN APPROVED ACCREDITATION ORGANIZATION SHALL SEND THE 23 DEPARTMENT ANY PRELIMINARY AND FINAL REPORT OF EACH INSPECTION AND 24 SURVEY AT THE TIME IT IS SENT TO THE HEALTH CARE FACILITY. A FINAL REPORT OF AN APPROVED ACCREDITATION ORGANIZATION 25 (2) 26 SHALL BE MADE IMMEDIATELY AVAILABLE TO THE PUBLIC ON REQUEST. 27 A PRELIMINARY OR FINAL REPORT OF AN APPROVED 28 ACCREDITATION ORGANIZATION IS NOT ADMISSIBLE IN EVIDENCE IN ANY CIVIL 29 ACTION OR PROCEEDING. THE DEPARTMENT MAY INSPECT AN ACCREDITED HEALTH CARE 30 (E) 31 FACILITY TO:
- 32 (1) DETERMINE COMPLIANCE WITH ANY QUALITY REQUIREMENT;
- FOLLOW UP ON ANY SERIOUS PROBLEM IDENTIFIED BY AN 34 APPROVED ACCREDITATION ORGANIZATION:
- INVESTIGATE A COMPLAINT; 35 (3)

- PARTICIPATE IN OR OBSERVE A SURVEY OF AN APPROVED 1 (4) 2 ACCREDITATION ORGANIZATION; OR
- VALIDATE THE FINDINGS OF AN APPROVED ACCREDITATION (5) 4 ORGANIZATION.
- ON A DETERMINATION BY THE SECRETARY THAT AN APPROVED
- 6 ACCREDITATION ORGANIZATION HAS FAILED TO MEET ITS OBLIGATIONS UNDER
- 7 THIS SECTION, THE SECRETARY MAY WITHDRAW:
- 8 THE APPROVAL FROM THE ACCREDITATION ORGANIZATION; AND (1)
- THE DEEMED STATUS GIVEN TO A HEALTH CARE FACILITY BY THE (2) 10 ACCREDITED ORGANIZATION.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take 12 effect October 1, 2006.