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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

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 21, 2005

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CHAPTER\_\_\_\_

#### 1 AN ACT concerning

- 2 Health Care Facilities and Laboratories Accreditation Organizations and Deeming
- 4 FOR the purpose of defining the term "health care facility " for the purpose of certain
- 5 licensing, accreditation, and regulatory provisions to include certain hospitals,
- 6 health maintenance organizations, freestanding ambulatory care facilities,
- assisted living facilities, laboratories, home health agencies, and residential
- 8 treatment centers; authorizing the Secretary of Health and Mental Hygiene to
- 9 accept all or part of certain reports of certain accreditation organizations as
- meeting certain licensure and review requirements and to grant a certain
- 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
- 17 organizations; authorizing the Department to conduct certain inspections;
- authorizing the Secretary to withdraw approval from an accreditation
- 19 organization or deemed status from a health care facility under certain
- 20 circumstances; repealing and altering certain provisions of law relating to
  - accreditation and deemed status of certain health care facilities; defining
- 22 certain terms; and generally relating to accreditation and deemed status of
- 23 certain health care facilities.

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- 24 BY repealing and reenacting, with amendments,
- 25 Article Health General
- 26 Section 17-202, 19-308, 19-309(b), 19-319(c), 19-323(a), 19-3B-03(d), 19-404,

1 2 3	19-1204, and 19-1207 Annotated Code of Maryland (2000 Replacement Volume and 2004 Supplement)					
4 5 6 7 8	BY repealing Article - Health - General Section 19-705.1(g)(5) and 19-1805(b) Annotated Code of Maryland (2000 Replacement Volume and 2004 Supplement)					
9 10 11 12 13 14	Section 19-2101 and 19-2102, to be under the new subtitle "Subtitle 21. Accreditation of Health Care Facilities" Annotated Code of Maryland					
15 16	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:					
17	Article - Health - General					
18	17-202.					
19 20	(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.					
24 25	(b) To assure compliance with the standards and requirements adopted in regulations pursuant to this subtitle, the Secretary shall:					
26 27	(1) Conduct an inspection of each medical laboratory for which a license to operate is sought; and					
28 29	(2) Conduct an inspection periodically of each medical laboratory for which a license has been issued.					
30 31	[(c) (1) A medical laboratory accredited by an organization approved by the Secretary shall be deemed to meet the:					
32 33	$\mbox{(i)} \qquad \mbox{State's inspection requirements under subsection (b)(2) of this} \\ \mbox{section; or} \\$					

			State's standards under this subtitle if the Secretary accrediting organization equivalent to the State's			
4 5	(2) The medical laboratory shall submit the report of the accrediting organization to the Secretary within 30 days of its receipt.					
		irpose of	retary may inspect a medical laboratory accredited by an a complaint investigation or to validate findings of the			
	this section, the Secre	tary shall	In addition to the regulations adopted under subsection (a) of adopt regulations establishing specific standards for n cytology, including regulations that:			
12		(i)	Limit the number of slides an individual may examine;			
13 14			Require that the examination of cytology slides be performed in license issued by the Secretary;			
15 16	cytology specimens or		Prohibit payment to cytotechnologists for the examination of n a piecework basis;			
17 18	of all negative gyneco		Require cytology laboratories to review no less than 10 percent lides;			
19 20			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			
26	specimens, make appr	opriate c	Require cytology laboratories to reject unsatisfactorily prepared omments regarding the quality of the specimen, and torily prepared specimens for 5 years subject to review			
28 29			Require cytology laboratories to maintain and store for 5 years ny slide that was examined;			
30		(ix)	Require all cytology reports to be retained for at least 10 years;			
31 32			Prohibit any person from sending cytology specimens to a ate laboratories, not licensed by the Department;			
		s in this S	Require all individuals who examine gynecological slides state to demonstrate satisfactory performance in an testing program; and			

	necessary to assure th reliable services.	(xii) at medica	Establish any additional standards the Secretary considers al laboratories engaged in cytology provide safe and
		provision	uirements of paragraph (1) of this subsection are in addition of this subtitle or relevant regulation adopted in vision of this subtitle governing medical laboratories.
9		y testing j	To assure compliance with standards adopted under subsection cretary shall adopt regulations to establish and conduct program for all cytology personnel that examine nens.
	(2) testing program shall Mental Hygiene who	be condu	logy proficiency tests under the State cytology proficiency acted by an employee of the Department of Health and
14		(i)	Hand carry all testing materials to the testing site; and
15		(ii)	Directly supervise the on-site proficiency testing.
	(3) the Secretary to cove program under this se	r the cost	cal laboratory shall pay the Department a fee established by of the laboratory's State cytology proficiency testing
19 20	(4) testing program that:	The Sec	retary shall adopt regulations for the cytology proficiency
21 22	and	(i)	Define satisfactory cytology proficiency testing performance;
23 24	testing program must	(ii) meet bef	Set standards and requirements that a cytology proficiency fore it can be designated an approved program.
	(5) proficiency testing profit of this subtitle.		retary may accept the testing results of an approved cytology s meeting the cytology proficiency testing requirement
28	19-308.		
	standards of services	for relate	all adopt reasonable rules and regulations that set ed institutions, nonaccredited hospitals, and ment centers in the following areas:
32	(1)	The care	e of patients;
33	(2)	The med	lical supervision of patients;
34	(3)	The phy	sical environment;
35	(4)	Disease	control;

30 reviewing compliance with licensure requirements for risk management, utilization

33 accredited residential treatment center, the Department shall use the current 34 applicable standards of the Joint Commission on Accreditation of Healthcare

When conducting an inspection of an accredited hospital or

At least 2 inspections a year of each related institution shall be

31 review, and physician credentialing under § 19-319 of this subtitle.

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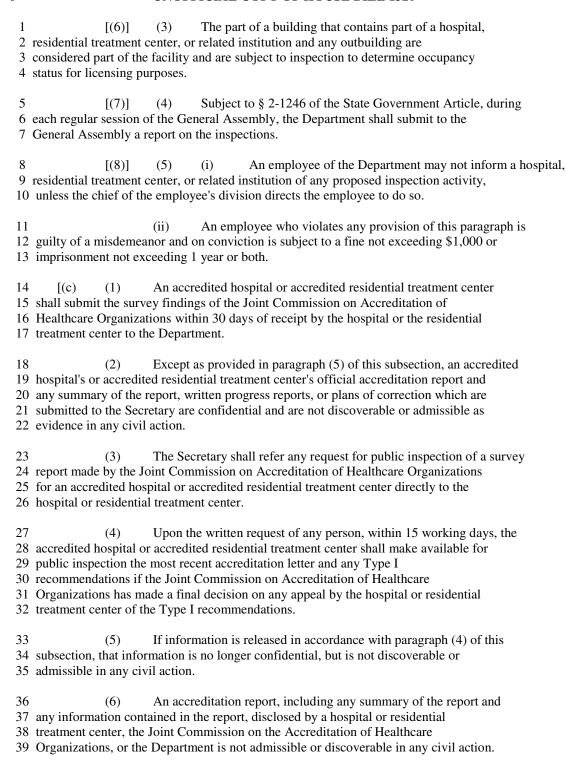
(4)

[(5)]

(2)

Organizations.]

37 unannounced.



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(7)

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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.]
4	19-309.
	(b) (1) To resolve expeditiously a complaint that alleges the existence of any nonlife-threatening deficiency, the Department may refer the complaint directly to the hospital or residential treatment center.
10	(2) If appropriate, issues relating to the practice of medicine or the licensure or conduct of a health professional shall be referred to the hospital or the residential treatment center and may be referred to the appropriate licensure board for resolution.
14 15	(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:
	(i) For an accredited hospital or accredited residential treatment center, the current applicable standards of review of the Joint Commission on Accreditation of Healthcare Organizations;
20 21	(ii) For a nonaccredited hospital or nonaccredited residential treatment center, the standards adopted by the Secretary under this subtitle;
	(iii) For an accredited or nonaccredited hospital that is a facility as defined under § 19-319.2 of this subtitle, the requirements of §§ 10-701 through 10-709 of this article; and
25 26	(iv) For an accredited or nonaccredited residential treatment center, the requirements of §§ 10-701 through 10-709 of this article.]
27	19-319.
	(c) (1) The applicant shall have a certificate of need, as required under Subtitle 1 of this title, for the hospital, residential treatment center, or related institution to be operated.
31 32	(2) The hospital, residential treatment center, or related institution to be operated shall[:
33 34	(i) Be an accredited hospital or accredited residential treatment center; or
35 36	$\begin{tabular}{ll} (ii) & Meet] MEET the requirements that the Secretary adopts under this subtitle and Subtitle 12 of this title. \end{tabular}$

1	19-323.
4	(a) (1) Except as provided under [paragraphs (2) and (3)] PARAGRAPH (2) of this subsection, a license for a 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.
6 7	[(2) A license for an accredited hospital expires when the certificate of accreditation expires.]
8 9	[(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.
10	19-3B-03.
11 12	(d) [(1) A freestanding ambulatory care facility accredited by an organization approved by the Secretary shall be deemed to meet State licensing requirements.
13 14	(2) (i) The freestanding ambulatory care facility shall submit the report of the accreditation organization to the Secretary within 30 days of its receipt.
15 16	(ii) All reports submitted under this paragraph shall be available for public inspection.
17	(3) The Secretary may:
18 19	(i) Inspect a freestanding ambulatory care facility for the purpose of a complaint investigation;
20 21	(ii) Inspect a freestanding ambulatory care facility to follow up on a serious problem identified in an accreditation report; and
22 23	(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.
27	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:

		efforts to	10 days of acceptance of a patient for skilled care, make and contact a physician to obtain the signed order required OF THIS SUBSECTION;		
4 5	(2) a physician obtained v	That accept patients for skilled care do so only on the signed order of within 28 days after acceptance;			
6	(3)	Adopt p	rocedures for the administration of drugs and biologicals;		
7	(4)	Maintai	n clinical records on all patients accepted for skilled care;		
8	(5)	Establis	Establish patient care policies and personnel policies;		
9 10	(6) available on an emerg		rvices available at least 8 hours a day, 5 days a week, and sis 24 hours a day, 7 days a week;		
l 1 l 2	(7) referral when stipulat		ervice available to an individual in need within 24 hours of a physician's order;		
	Have a designated supervisor of patient care who is a full-time employee of the agency and is available at all times during operating hours and additionally as needed; and				
	(9) year of supervisory e public health program	xperience	the administrator of the agency a person who has at least 1 e in hospital management, home health management, or ement and who is:		
19		(i)	A licensed physician;		
20		(ii)	A registered nurse; or		
21 22	field.	(iii)	A college graduate with a bachelor's degree in a health-related		
23	(c) The rule	es and reg	gulations may include provisions that:		
24	(1)	Deal wit	th the establishment of home health agencies;		
25 26	(2) professional group th		each home health agency to have its policies established by a es at least:		
27		(i)	1 physician;		
28		(ii)	1 registered nurse;		
29		(iii)	1 representative of another offered service; and		
30		(iv)	1 public member;		
31	(3)	Govern	the services provided by the home health agencies;		

1 2	(4) treatment to be provide				
3	(5)	Govern supervision of the services, as appropriate, by:			
4		(i) A physician;			
5		(ii)	A registered nurse; or		
6 7	advanced training to s		Another health professional who is qualified sufficiently by the same kind of services in a hospital; and		
8 9	(6) utilization statistics.	Require	submission of an annual report which includes service		
10 11	[(d) (1) Secretary shall be dec		health agency accredited by an organization approved by the neet State licensing regulations.		
12 13	(2) accreditation organization		The home health agency shall submit the report of the ne Secretary within 30 days of its receipt.		
14 15	for public inspection.	(ii)	All reports submitted under this paragraph shall be available		
16	(3)	The Seco	retary may:		
17 18	investigation;	(i)	Inspect the home health agency for the purpose of a complaint		
19 20	problem identified in		Inspect the home health agency to follow up on a serious ditation organization's report; and		
	agencies in the State report.]		Annually, conduct a survey of up to 5 percent of all home health e the findings of an accreditation organization's		
24 25	[(e)] (D) home health agency t		visions of this section do not waive the requirement for a a certificate of need.		
26	19-705.1.				
	(g) [(5) accrediting organizat subtitle.	(i) ion as me	The Secretary may accept all or part of a report of an approved eting the external review requirements under this		
32		l accrediti	Except as provided in subparagraph (iii) of this paragraph, a ing organization used by the Department as meeting atts under this subtitle shall be made available to the		

3	(iii) The Department may not disclose and shall treat as 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.				
5 6	organization	to:	(iv)	The Dep	partment may inspect a facility of a health maintenance
7 8	established u	nder this	subtitle;	1.	Determine compliance with any quality requirement
9 10	accrediting of	organizat	ion; or	2.	Follow up on a serious problem identified by an approved
11				3.	Investigate a complaint.]
12	19-1204.				
13	[(a)]	A comp	rehensive	rehabili	tation facility shall[:
		(1) e standard			abilitation programs that have been accredited by ion on Accreditation of Rehabilitation
	Facilities to Accreditatio		the Seci	retary any	mmission on Accreditation of Rehabilitation y information obtained by the Commission on es during:
20			(i)	The acc	reditation process; and
21			(ii)	Any ins	pection; and
22		(3)	Meet an	y other st	andard that the Secretary may adopt by regulation.
25 26	(b) To allow a comprehensive rehabilitation facility to achieve accreditation by the Commission on Accreditation of Rehabilitation Facilities as required by subsection (a) of this section for any rehabilitation program that the facility provides, the Secretary may waive the accreditation requirement for the facility for no more than 2 years from:				
28		(1)	July 1, 1	986; or	
29 30	STANDARI	(2) O THAT			h the facility begins operation] MEET ANY RY ADOPTS BY REGULATION.
31	19-1207.				
	(a) rehabilitation rehabilitation	n service	s unless t		nself out as providing a complete array of a provides comprehensive physical

1 2	(b) A health care facility may not provide or hold itself out as providing any specialized rehabilitation program unless[:					
	(1) The program has been accredited by the Commission on Accreditation of Rehabilitation Facilities to provide the particular specialized rehabilitation program; or					
8	(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.					
10 11	(c) A person may not provide comprehensive physical rehabilitation services unless the person meets the requirements of this subtitle.					
12	19-1805.					
		The Secretary may accept all or part of a report of an approved is meeting the State licensing requirements for renewal of a red living facility program.				
	approved accrediting orga	The Secretary may not accept all or part of a report of an nization as meeting the State licensing requirements for an assisted living facility program.				
	` /	The assisted living facility program shall submit the report of n to the Secretary within 30 days of the receipt of the report ity program.				
24	Department as meeting the	The report of an accrediting organization used by the e State licensing requirements for renewal of a license to facility program shall be made available to the public on				
26	(3) The	Secretary may inspect an assisted living facility program to:				
27	(i)	Investigate a complaint;				
28 29	(ii) accrediting organization; of	Follow up on a serious problem identified by an approved or				
30	(iii)	Validate findings of an approved accrediting organization.]				
31		SUBTITLE 21. ACCREDITATION OF HEALTH CARE FACILITIES				
32	19-2101.					
33 34	(A) IN THIS SUI	BTITLE THE FOLLOWING WORDS HAVE THE MEANINGS				

- 1 (B) "ACCREDITATION ORGANIZATION" MEANS A PRIVATE ENTITY THAT 2 CONDUCTS INSPECTIONS AND SURVEYS OF HEALTH CARE FACILITIES BASED ON
- 3 NATIONALLY RECOGNIZED AND DEVELOPED STANDARDS.
- 4 (C) "DEEMED STATUS" MEANS A STATUS UNDER WHICH A HEALTH CARE
- 5 FACILITY MAY BE EXEMPT FROM ROUTINE SURVEYS CONDUCTED BY THE
- 6 DEPARTMENT.
- 7 (D) "HEALTH CARE FACILITY" MEANS:
- 8 (1) A HOSPITAL AS DEFINED IN § 19-301(B) OF THIS TITLE;
- 9 (2) A HEALTH MAINTENANCE ORGANIZATION AS DEFINED IN § 19-701(G)
- 10 OF THIS ARTICLE;
- 11 (3) A FREESTANDING AMBULATORY CARE FACILITY AS DEFINED § IN
- 12 19-3B-01 OF THIS TITLE;
- 13 (4) AN ASSISTED LIVING FACILITY AS DEFINED IN § 19-1801 OF THIS
- 14 TITLE;
- 15 (5) A LABORATORY AS DEFINED IN § 17-201 OF THIS ARTICLE;
- 16 (6) A HOME HEALTH AGENCY AS DEFINED IN § 19-401 OF THIS TITLE;
- 17 AND
- 18 (7) A RESIDENTIAL TREATMENT CENTER AS DEFINED IN § 19-301 OF
- 19 THIS TITLE; AND
- 20 (8) A COMPREHENSIVE REHABILITATION FACILITY AS DEFINED IN §
- 21 19-1201 OF THIS TITLE.
- 22 19-2102.
- 23 (A) ACCREDITATION ORGANIZATIONS SHALL APPLY TO THE SECRETARY FOR
- 24 APPROVAL.
- 25 (B) PRIOR TO APPROVAL OF AN ACCREDITATION ORGANIZATION, THE
- **26 SECRETARY SHALL:**
- 27 (1) DETERMINE THAT THE STANDARDS OF THE ACCREDITATION
- 28 ORGANIZATION ARE EQUAL TO OR MORE STRINGENT THAN EXISTING STATE
- 29 REQUIREMENTS;
- 30 (2) EVALUATE THE SURVEY OR INSPECTION PROCESS OF THE
- 31 ACCREDITATION ORGANIZATION TO ENSURE THE INTEGRITY OF THE SURVEY
- 32 PROCESS; AND
- 33 (3) ENTER INTO A FORMAL WRITTEN AGREEMENT WITH THE
- 34 ACCREDITATION ORGANIZATION THAT INCLUDES REQUIREMENTS FOR:

(I) NOTICE OF ALL SURVEYS AND INSPECTIONS; 1 SHARING OF COMPLAINTS AND OTHER RELEVANT 2 (II)3 INFORMATION: PARTICIPATION OF THE DEPARTMENT IN ACCREDITATION (III) 5 ORGANIZATION ACTIVITIES; AND (IV) ANY OTHER PROVISION NECESSARY TO ENSURE THE 7 INTEGRITY OF THE ACCREDITATION AND LICENSURE PROCESS. WHEN AN APPROVED ACCREDITATION ORGANIZATION HAS ISSUED A 8 (C) (1) 9 FINAL REPORT FINDING A HEALTH CARE FACILITY TO BE IN SUBSTANTIAL 10 COMPLIANCE WITH THE ACCREDITATION ORGANIZATION'S STANDARDS, THE 11 DEPARTMENT SHALL ACCEPT THE REPORT AS EVIDENCE THAT THE HEALTH CARE 12 FACILITY HAS MET STATE LICENSURE REQUIREMENTS AND SHALL GRANT THE 13 HEALTH CARE FACILITY DEEMED STATUS. 14 A HEALTH CARE FACILITY THAT FAILS TO ACHIEVE SUBSTANTIAL (2) 15 COMPLIANCE WITH THE STANDARDS OF AN APPROVED ACCREDITATION 16 ORGANIZATION MAY BE SUBJECT TO THE PROVISIONS OF § 19-360 OF THIS TITLE. AN APPROVED ACCREDITATION ORGANIZATION SHALL SEND THE 17 (D) (1) 18 DEPARTMENT ANY PRELIMINARY AND FINAL REPORT OF EACH INSPECTION AND 19 SURVEY AT THE TIME IT IS SENT TO THE HEALTH CARE FACILITY. A FINAL REPORT OF AN APPROVED ACCREDITATION ORGANIZATION 21 SHALL BE MADE IMMEDIATELY AVAILABLE TO THE PUBLIC ON REQUEST. A PRELIMINARY OR FINAL REPORT OF AN APPROVED 22 23 ACCREDITATION ORGANIZATION IS NOT ADMISSIBLE IN EVIDENCE IN ANY CIVIL 24 ACTION OR PROCEEDING. THE DEPARTMENT MAY INSPECT AN ACCREDITED HEALTH CARE 25 (E) 26 FACILITY TO: 27 (1) DETERMINE COMPLIANCE WITH ANY QUALITY REQUIREMENT; FOLLOW UP ON ANY SERIOUS PROBLEM IDENTIFIED BY AN 28 (2)29 APPROVED ACCREDITATION ORGANIZATION; 30 (3) INVESTIGATE A COMPLAINT; (4) PARTICIPATE IN OR OBSERVE A SURVEY OF AN APPROVED 32 ACCREDITATION ORGANIZATION; OR

VALIDATE THE FINDINGS OF AN APPROVED ACCREDITATION

(5)

34 ORGANIZATION.

- 1 (F) ON A DETERMINATION BY THE SECRETARY THAT AN APPROVED
- 2 ACCREDITATION ORGANIZATION HAS FAILED TO MEET ITS OBLIGATIONS UNDER
- 3 THIS SECTION, THE SECRETARY MAY WITHDRAW:
- 4 (1) THE APPROVAL FROM THE ACCREDITATION ORGANIZATION; AND
- 5 (2) THE DEEMED STATUS GIVEN TO A HEALTH CARE FACILITY BY THE
- 6 ACCREDITED ORGANIZATION.
- 7 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
- 8 effect October 1, 2005.