

## THE GENERAL ASSEMBLY OF PENNSYLVANIA

# HOUSE BILL

## No. 1570 Session of 2011

INTRODUCED BY REICHLEY, CLYMER, CUTLER, EVERETT, GILLESPIE,  
GODSHALL, GROVE, HARHART, HESS, LONGIETTI, MILLER, WATSON,  
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MAY 23, 2011

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES,  
AS AMENDED, JUNE 6, 2012

## AN ACT

1 Amending the act of July 19, 1979 (P.L.130, No.48), entitled "An  
2 act relating to health care; prescribing the powers and  
3 duties of the Department of Health; establishing and  
4 providing the powers and duties of the State Health  
5 Coordinating Council, health systems agencies and Health Care  
6 Policy Board in the Department of Health, and State Health  
7 Facility Hearing Board in the Department of Justice;  
8 providing for certification of need of health care providers  
9 and prescribing penalties," in licensing of health care  
10 facilities, further providing for definitions, AND for  
11 licensure, PROVIDING FOR MEDICAL STAFF REQUIREMENTS FOR  
12 HOSPITAL LICENSURE, FURTHER PROVIDING for term and content of  
13 license and for reliance on accrediting agencies and Federal  
14 Government; AND PROVIDING FOR RELIANCE ON NATIONAL  
15 ACCREDITATION ORGANIZATIONS FOR HOSPITALS.

16 The General Assembly of the Commonwealth of Pennsylvania  
17 hereby enacts as follows:

18 ~~Section 1. The definition of "health care facility" in~~  
19 ~~section 802.1 of the act of July 19, 1979 (P.L.130, No.48),~~  
20 ~~known as the Health Care Facilities Act, amended July 7, 2006~~  
21 ~~(P.L.334, No.69), is amended and the section is amended by~~  
22 ~~adding definitions to read:~~  
23 ~~Section 802.1. Definitions.~~

~~The following words and phrases when used in this chapter shall have, unless the context clearly indicates otherwise, the meanings given them in this section:~~

~~\*\*\*~~

~~"Health care facility." [For purposes of Chapter 8, a health care facility includes, but is not limited to, a general, chronic disease or other type of hospital, a home health care agency, a home care agency, a hospice, a long term care nursing facility, cancer treatment centers using radiation therapy on an ambulatory basis, an ambulatory surgical facility, a birth center regardless of whether such health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government. The department shall have the authority to license other health care facilities as may be necessary due to emergence of new modes of health care. When the department so finds, it shall publish its intention to license a particular type of health care facility in the Pennsylvania Bulletin in accordance with the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act." The term health care facility shall not include an office used primarily for the private practice of a health care practitioner, nor a program which renders treatment or care for drug or alcohol abuse or dependence unless located within a health facility, nor a facility providing treatment solely on the basis of prayer or spiritual means. The term health care facility shall not apply to a facility which is conducted by a religious organization for the purpose of providing health care services exclusively to clergymen or other persons in a religious profession who are members of a religious denomination.] For the purposes of this act, the term shall include hospitals, cancer treatment centers~~

~~using radiation therapy on an ambulatory basis, ambulatory surgical facilities, specialized health care services and outpatient health care facilities regardless of whether the health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government. The term shall not include an office used primarily for the private practice of a health care practitioner nor a program which renders treatment or care for drug or alcohol abuse or dependence unless located within a health care facility, nor a facility providing treatment solely on the basis of prayer or spiritual means. The term shall not apply to a facility which is conducted by a religious organization for the purpose of providing health care services exclusively to the clergymen or other persons in a religious profession who are members of a religious denomination.~~

~~\* \* \*~~

~~"Outpatient health care facility." For the purposes of this act, the term shall be defined as a facility, whether fixed or mobile, providing diagnostic, therapeutic, treatment or rehabilitation services on an outpatient basis or to individual patients for less than a 24 hour consecutive period, by or under the supervision of physicians or other clinical staff in accordance with their scope of practice. The term does not include an office used primarily for the private practice of a health care practitioner, but does include clinics and group practice facilities providing diagnostic and treatment services other than primary care in a specific specialized area of medicine. Outpatient health care services provided under the license of a hospital are excluded from this definition. Outpatient services on the site of a hospital but not provided~~

~~under the hospital license are included.~~

~~"Outpatient health care services." The term includes  
emergency services, cardiac catheterization, cancer treatment  
services involving radiation therapy, imaging services, pain  
management services, burn center services, ambulatory surgery  
services, dialysis services or any other clinical service deemed  
by the Department of Health and published in the Pennsylvania  
Bulletin to be subject to this act.~~

~~"Physical status." The American Society of Anesthesiologists  
Physical Status Classification System.~~

~~"Specialized health care services." Certain diagnostic,  
treatment or rehabilitative services which involve highly  
technical medical procedures and require extraordinary expertise  
and resources to be effective and safe as determined by the  
Department of Health.~~

~~Section 2. Section 806(a), (b) and (c) of the act, amended  
December 18, 1992 (P.L.1602, No.179) and October 16, 1998  
(P.L.777, No.95), are amended and the section is amended by  
adding subsections to read:~~

~~Section 806. Licensure.~~

~~(a) License required. No person shall maintain or operate  
or hold itself out to be a health care facility or provide  
specialized services without first having obtained a license  
[therefor] issued by the department. [No health care facility  
can be a provider of medical assistance services unless it is  
licensed by the department and certified as a medical assistance  
provider.]:~~

~~(1) Facilities or specialized health care services  
accredited by a national accrediting organization approved by  
the Centers for Medicare and Medicaid Services (CMS) shall be~~

~~deemed to meet licensure requirements and shall be issued a license by the department.~~

~~(2) Facilities not accredited by a CMS approved national accrediting organization shall be required to meet the applicable Medicare Conditions of Participation or Medicare Conditions of Coverage.~~

~~(3) Facilities or specialized health care services that are not accredited and do not participate in Medicare shall be required to comply with regulations adopted by the department.~~

~~(a.1) Additional requirements. Specific facilities or specialized health care services shall be required, as a condition of licensure, to do the following:~~

~~(1) Class A ambulatory surgical facilities (ASF) shall meet the following criteria:~~

~~(i) A license is not required for the operation of a Class A ASF; however, the facility shall be accredited by the Accreditation Association for Ambulatory Health Care, the Joint Commission on the Accreditation of Health Care Organizations, the American Association for the Accreditation of Ambulatory Surgical Facilities or another nationally recognized accrediting organization acknowledged by the Medicare program in order to be identified as providing ambulatory service.~~

~~(ii) A Class A ASF shall register with the department and shall forward a copy of its accreditation survey to the department.~~

~~(iii) The Class A ASF must provide the following information with the registration form and update the department on an annual basis:~~

1                   ~~(A) A list of operative procedures proposed to~~  
2                   ~~be performed at the facility and the ages of the~~  
3                   ~~patients to be served.~~

4                   ~~(B) The type of anesthetic proposed to be used~~  
5                   ~~for each operative procedure.~~

6                   ~~(C) The facility's current accreditation survey~~  
7                   ~~and the designation of accreditation status by the~~  
8                   ~~nationally recognized accrediting organization.~~

9                   ~~(D) Other information the department deems~~  
10                   ~~necessary for registration.~~

11                   ~~(2) A license shall be obtained to operate a~~  
12                   ~~freestanding Class B or Class C ASF.~~

13                   ~~(3) An ASF license shall designate the licensed facility~~  
14                   ~~as either a Class B or Class C ASF.~~

15                   ~~(4) An applicant for a license to operate an ASF shall~~  
16                   ~~request licensure by the department by means of a written~~  
17                   ~~communication which sets forth:~~

18                   ~~(i) A list of operative procedures proposed to be~~  
19                   ~~performed at the facility and the ages of the patients to~~  
20                   ~~be served.~~

21                   ~~(ii) The highest level of anesthetic proposed to be~~  
22                   ~~used for each proposed operative procedure.~~

23                   ~~(iii) The highest physical status proposed to~~  
24                   ~~receive ambulatory surgery at the facility.~~

25                   ~~(iv) A statement from the applicant which may be~~  
26                   ~~accompanied by a written opinion from a nationally~~  
27                   ~~recognized accrediting body stating the most appropriate~~  
28                   ~~facility class.~~

29                   ~~(5) If a facility desires to change its classification~~  
30                   ~~level from a Class B enterprise to a Class C enterprise, the~~

~~facility shall request and obtain a license prior to providing services to patients with a physical status of ASF Class III or level III.~~

~~(6) The department may enter and inspect an ASF Class A, B or C, at any time, announced or unannounced, to investigate any complaints. The department may mandate closure of an ASF that the department determines to be providing substandard care or for any other lawful reason.~~

~~(7) Criteria for ambulatory surgery:~~

~~(i) Ambulatory surgical procedures are limited to those procedures that do not exceed a total of four hours of operating time and four hours of directly supervised recovery.~~

~~(ii) The time limits may be exceeded only if the patient's condition demands care or recovery beyond the four hour limit and the need for additional time could not have been anticipated prior to surgery.~~

~~(iii) The surgical procedure shall not require more than local or regional anesthesia or less than four hours of general anesthesia.~~

~~(iv) The procedure may not be of a type that is associated with the risk of extreme blood loss or directly involves major blood vessels.~~

~~(v) The surgery may not require major or prolonged invasion of body cavities.~~

~~(vi) The procedure may not be an emergency or be life threatening in nature unless no hospitals are available for the procedure and the need for surgery could not have been anticipated.~~

~~(vii) The practitioner performing the surgery is~~

~~responsible for obtaining the informed consent of the patient for disclosure to the patient of the risks, benefits and alternatives associated with the anesthesia which will be administered, the procedure that will be performed and the comparative risks, benefits and alternatives to performance of the procedure in the ASF.~~

~~(viii) The department may issue interpretations of this subsection, which apply to the question of whether the performance of certain surgical procedures will require licensure as an ASF.~~

~~(ix) Interpretations adopted by the department shall be submitted to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin and the Pennsylvania Code as a statement of policy of the department.~~

~~(a.2) Pediatric patients. The following criteria must be met to perform ambulatory surgery on patients that are under 18 years of age:~~

~~(1) A child under six months of age shall not be treated in an ASF.~~

~~(2) The medical record shall include documentation that the child's primary care provider was notified by the surgeon in advance of the performance of a procedure in an ASF and that an opinion was sought from the primary care provider regarding the appropriateness of the use of an ASF for the proposed procedure. When an opinion from the child's primary care provider is not obtainable, the medical record shall include documentation which explains why an opinion could not be obtained.~~

~~(3) Anesthesia services shall be provided by an~~



~~anesthesiologist who is a graduate of an anesthesiology  
residency program accredited by the Accreditation Council for  
Graduate Medical Education or its equivalent or by a  
certified registered nurse anesthetist trained in pediatric  
anesthesia either of whom shall have documented demonstrated  
historical and continuous competence in the care of these  
patients.~~

~~(4) The practitioner performing the surgery shall be  
either board certified by or have obtained preboard  
certification status with the American Board of Medical  
Specialties, the American Osteopathic Board of Surgery, the  
American Board of Podiatric Surgery or the American Board of  
Oral and Maxillofacial Surgery.~~

~~(5) A medical professional who has successfully  
completed a course in advanced pediatric life support offered  
by the American Academy of Pediatrics and either the American  
College of Emergency Physicians or the American Heart  
Association shall be present in the facility.~~

~~(a.3) Specialized health care services. The department  
shall annually determine the types of specialized health care  
services to be licensed under the provisions of this chapter:~~

~~(1) The department shall base its determination on the  
following factors:~~

~~(i) Whether the quality of the services to be  
offered is likely to be compromised through insufficient  
volumes or utilization.~~

~~(ii) The cost and specialized expertise necessary  
for safe and effective care.~~

~~(iii) Whether the service dependent is upon the  
availability of scarce natural resources such as human~~

organs.

~~(iv) Whether the service involves the use of new  
medical technology.~~

~~(v) Consideration shall be given to the availability  
and accessibility of specialized health care services to  
accommodate populations in this Commonwealth.~~

~~(2) Exceptions may be granted by the department to  
accommodate populations in this Commonwealth based on  
availability and accessibility of health care services.~~

~~(b) Development of regulations. In developing rules and  
regulations for licensure of facilities or specialized health  
care services not accredited and who do not participate in  
Medicare, the department shall [take] adopt reasonable rules and  
regulations, taking into consideration [Federal certification  
standards and the standards of other third party payors for  
health care services and such nationally recognized accrediting  
agencies as the department may find appropriate.] applicable  
standards of nationally recognized accrediting organizations  
applicable to the service or setting. At a minimum, the  
regulations shall address the following areas:~~

~~(1) The care of patients.~~

~~(2) The medical supervision of patients.~~

~~(3) The physical environment.~~

~~(4) Infection control.~~

~~(5) Quality assurance.~~

~~(6) Transfer protocols or procedures with receiving  
facilities, where applicable.~~

~~(7) Sanitation.~~

~~(8) Safety.~~

~~(9) Dietary matters.~~

1 ~~(c) Fire and emergency standards. Notwithstanding any other~~  
2 ~~provision of law other than standards required for Federal~~  
3 ~~certification by that type of health care facility in the~~  
4 ~~Medicare or Medicaid program[, no]:~~

5 ~~(1) No health care facility shall be required to satisfy~~  
6 ~~any regulation relating to fire or similar emergency~~  
7 ~~circumstance more stringent than those required [of hospitals~~  
8 ~~by the Joint Commission on Accreditation of Health~~  
9 ~~Organizations or such nationally recognized accrediting~~  
10 ~~agencies as the department may find appropriate, and the~~  
11 ~~department shall adopt and enforce the appropriate] by the~~  
12 ~~accrediting organization, and the department shall adopt and~~  
13 ~~enforce these standards.~~

14 ~~(2) Nonaccredited, non-Medicare participating facilities~~  
15 ~~shall comply with the Life Safety Code standards for medical~~  
16 ~~facilities defined by the National Fire Protection~~  
17 ~~Association.~~

18 ~~\* \* \*~~

19 ~~Section 3. Sections 809(a) and (d) and 810(a) of the act,~~  
20 ~~amended December 18, 1992 (P.L.1602, No.179), are amended to~~  
21 ~~read:~~

22 ~~Section 809. Term and content of license.~~

23 ~~(a) Contents. All licenses issued by the department under~~  
24 ~~this chapter shall:~~

25 ~~(1) be issued for a specified length of time as follows,~~  
26 ~~including the provision of section 804(b):~~

27 ~~(i) all accredited health care facilities [other~~  
28 ~~than hospitals for a period of one year, and for~~  
29 ~~hospitals for a period of two years], for the duration of~~  
30 ~~the accreditation cycle in good standing with the~~

~~expiration date to be the last day of the month in which  
license is issued;~~

~~(ii) provisional licenses for the length of time to  
be determined by the department upon issuance of the  
provisional license; and~~

~~(iii) all nonaccredited facilities' time frames  
shall correspond to the time frames for accredited  
facilities;~~

~~(2) be on a form prescribed by the department;~~

~~(3) not be transferable except upon prior written  
approval of the department;~~

~~(4) be issued only to the health care provider and for  
the health care facility [or] facilities or specialized  
health care services named in the application;~~

~~(5) specify the maximum number of beds, if any, to be  
used for the care of patients in the facility at any one  
time; and~~

~~(6) specify limitations which have been placed on the  
facility.~~

~~\*\*\*~~

~~(d) Use of beds in excess of maximum. Except in case of  
[extreme emergency] natural disasters, catastrophes, acts of  
bio terrorism, epidemics or other emergencies, no license shall  
permit the use of beds for inpatient use in the licensed  
facility in excess of the maximum number set forth in the  
license [without first obtaining written permission from the  
department: Provided, That during the period of a license, a  
health care facility may without the prior approval of the  
department increase the total number of beds by not more than  
ten beds or 10% of the total bed capacity, whichever is less].~~

~~Section 810. Reliance on accrediting agencies and Federal Government.~~

~~(a) Reports of other agencies. After a provider has been licensed or approved to operate a health care facility or provide specialized health care services for at least [two] three years under this or prior acts, none of which has been pursuant to a provisional license, the department [may] shall rely on the reports of the Federal Government or nationally recognized accrediting [agencies to the extent those standards are determined by the department to be similar to regulations of the department and if] agencies' current applicable standards as long as the provider agrees to:~~

~~(1) direct the agency or government to provide a copy of its findings to the department; and~~

~~(2) permit the department to inspect those areas or programs of the health care facility [not covered by the agency or government inspection or] where the agency or government report discloses more than a minimal violation of [department regulations] current standards.~~

~~\* \* \*~~

~~Section 4. This act shall take effect in 60 days.~~

SECTION 1. SECTION 802.1 OF THE ACT OF JULY 19, 1979  
(P.L.130, NO.48), KNOWN AS THE HEALTH CARE FACILITIES ACT, IS  
AMENDED BY ADDING DEFINITIONS TO READ:

SECTION 802.1. DEFINITIONS.

THE FOLLOWING WORDS AND PHRASES WHEN USED IN THIS CHAPTER  
SHALL HAVE, UNLESS THE CONTEXT CLEARLY INDICATES OTHERWISE, THE  
MEANINGS GIVEN THEM IN THIS SECTION:

\* \* \*

"DEEMED STATUS." A PROCESS UNDER WHICH A HOSPITAL MAY BE



1 EXEMPT FROM ROUTINE LICENSURE RENEWAL SURVEYS CONDUCTED BY THE  
2 DEPARTMENT OF HEALTH.

3 \* \* \*

4 "NATIONAL ACCREDITED ORGANIZATION." A NONGOVERNMENTAL  
5 ORGANIZATION THAT HAS BEEN AUTHORIZED BY THE CENTERS FOR  
6 MEDICARE AND MEDICAID SERVICES (CMS) TO CONDUCT HOSPITAL SURVEYS  
7 TO ENSURE COMPLIANCE WITH THE CMS CONDITIONS OF PARTICIPATION.

8 SECTION 2. SECTION 806(A), (B) AND (C) OF THE ACT, AMENDED  
9 DECEMBER 18, 1992 (P.L.1602, NO.179) AND OCTOBER 16, 1998  
10 (P.L.777, NO.95), ARE AMENDED AND THE SECTION IS AMENDED BY  
11 ADDING A SUBSECTION TO READ:

12 SECTION 806. LICENSURE.

13 (A) LICENSE REQUIRED.--[NO] EXCEPT AS PROVIDED FOR IN  
14 SUBSECTION (I), NO PERSON SHALL MAINTAIN OR OPERATE OR HOLD  
15 ITSELF OUT TO BE A HEALTH CARE FACILITY WITHOUT FIRST HAVING  
16 OBTAINED A LICENSE THEREFOR ISSUED BY THE DEPARTMENT. NO HEALTH  
17 CARE FACILITY CAN BE A PROVIDER OF MEDICAL ASSISTANCE SERVICES  
18 UNLESS IT IS LICENSED BY THE DEPARTMENT AND CERTIFIED AS A  
19 MEDICAL ASSISTANCE PROVIDER.

20 (B) DEVELOPMENT OF REGULATIONS.--[IN] EXCEPT AS PROVIDED FOR  
21 IN SUBSECTION (I), IN DEVELOPING RULES AND REGULATIONS FOR  
22 LICENSURE THE DEPARTMENT SHALL TAKE INTO CONSIDERATION FEDERAL  
23 CERTIFICATION STANDARDS AND THE STANDARDS OF OTHER THIRD PARTY  
24 PAYORS FOR HEALTH CARE SERVICES AND SUCH NATIONALLY RECOGNIZED  
25 ACCREDITING AGENCIES AS THE DEPARTMENT MAY FIND APPROPRIATE.

26 (C) FIRE AND EMERGENCY STANDARDS.--[NOTWITHSTANDING] EXCEPT  
27 AS PROVIDED FOR IN SUBSECTION (I), NOTWITHSTANDING ANY OTHER  
28 PROVISION OF LAW OTHER THAN STANDARDS REQUIRED FOR FEDERAL  
29 CERTIFICATION BY THAT TYPE OF HEALTH CARE FACILITY IN THE  
30 MEDICARE OR MEDICAID PROGRAM, NO HEALTH CARE FACILITY SHALL BE

1 REQUIRED TO SATISFY ANY REGULATION RELATING TO FIRE OR SIMILAR  
2 EMERGENCY CIRCUMSTANCE MORE STRINGENT THAN THOSE REQUIRED OF  
3 HOSPITALS BY THE JOINT COMMISSION ON ACCREDITATION OF HEALTH  
4 ORGANIZATIONS OR SUCH NATIONALLY RECOGNIZED ACCREDITING AGENCIES  
5 AS THE DEPARTMENT MAY FIND APPROPRIATE, AND THE DEPARTMENT SHALL  
6 ADOPT AND ENFORCE THE APPROPRIATE STANDARDS.

7 \* \* \*

8 (I) HOSPITALS.--

9 (1) IN ISSUING A LICENSE TO A HOSPITAL, THE DEPARTMENT  
10 SHALL, AT THE REQUEST OF THE HOSPITAL, RELY ON THE REPORTS OF  
11 NATIONAL ACCREDITATION ORGANIZATIONS DESIGNATED AS ACCEPTABLE  
12 TO THE DEPARTMENT PURSUANT TO THE REQUIREMENTS SET FORTH IN  
13 SECTION 810.1 AND SHALL ISSUE A LICENSE TO A HOSPITAL THAT  
14 RECEIVED APPROVAL OR ACCREDITATION FROM SUCH A DESIGNATED  
15 ORGANIZATION.

16 (2) A HOSPITAL THAT IS NOT ACCREDITED BY A NATIONAL  
17 ACCREDITATION ORGANIZATION OR DOES NOT REQUEST THAT THE  
18 DEPARTMENT RELY ON SUCH ACCREDITATION SHALL BE REQUIRED TO  
19 COMPLY WITH REGULATIONS ADOPTED BY THE DEPARTMENT.

20 (3) THIS SUBSECTION SHALL NOT BE CONSTRUED AS A  
21 LIMITATION ON THE DEPARTMENT'S RIGHT OF INSPECTION OTHERWISE  
22 PERMITTED UNDER SECTION 813, INCLUDING, BUT NOT LIMITED TO,  
23 THE RIGHT TO INSPECT IN RESPONSE TO COMPLAINTS OR OTHER  
24 REPORTS MADE TO THE DEPARTMENT.

25 (4) A HOSPITAL THAT IS ACCREDITED BY A NATIONAL  
26 ACCREDITATION ORGANIZATION SHALL COMPLY WITH THE STANDARDS  
27 ESTABLISHED BY THAT ORGANIZATION. ANY INSPECTION OF A  
28 PARTICIPATING ACCREDITED HOSPITAL SHALL BE BASED ON THE  
29 STANDARDS ESTABLISHED BY THE NATIONAL ACCREDITATION  
30 ORGANIZATION THAT ACCREDITS THE HOSPITAL AND STATE LAW.

1           (5) A HOSPITAL THAT IS NOT ACCREDITED BY A NATIONAL  
2           ACCREDITATION ORGANIZATION SHALL COMPLY WITH THE FOLLOWING:

3           (I) THE LICENSURE REGULATIONS ADOPTED BY THE  
4           DEPARTMENT.

5           (II) IN REVISING THE RULES AND REGULATIONS FOR  
6           LICENSURE OF HOSPITALS NOT ACCREDITED BY A NATIONAL  
7           ACCREDITATION ORGANIZATION, THE DEPARTMENT SHALL TAKE  
8           INTO CONSIDERATION APPLICABLE STANDARDS OF NATIONALLY  
9           RECOGNIZED ACCREDITATION ORGANIZATIONS SPECIFIC TO  
10          HOSPITALS. AT A MINIMUM, THE REGULATIONS SHALL ADDRESS  
11          THE FOLLOWING AREAS:

12           (A) THE CARE OF PATIENTS;

13           (B) THE MEDICAL SUPERVISION OF PATIENTS;

14           (C) THE PHYSICAL ENVIRONMENT;

15           (D) INFECTION CONTROL;

16           (E) QUALITY ASSURANCE;

17           (F) TRANSFER PROTOCOLS;

18           (G) SANITATION;

19           (H) SAFETY; AND

20           (I) DIETARY MATTERS.

21          (6) ALL HOSPITALS, WHETHER LICENSED THROUGH  
22          ACCREDITATION OR COMPLIANCE WITH THE DEPARTMENT'S  
23          REGULATIONS, SHALL:

24           (I) COMPLY WITH MEDICAL STAFF REQUIREMENTS SET FORTH  
25           IN SECTION 806.5.

26           (II) SUBMIT PLANS FOR NEW CONSTRUCTION AND  
27           RENOVATION OF FACILITIES TO THE DEPARTMENT AND MUST  
28           RECEIVE APPROVAL FROM THE DEPARTMENT BEFORE PROVIDING  
29           SERVICES IN THE NEWLY CONSTRUCTED OR RENOVATED AREAS.

30          (7) THE DEPARTMENT SHALL REVIEW AND REVISE THE



1 REGULATIONS PROMULGATED UNDER THIS SECTION NO LESS OFTEN THAN  
2 EVERY FIVE YEARS.

3 SECTION 3. THE ACT IS AMENDED BY ADDING A SECTION TO READ:  
4 SECTION 806.5. MEDICAL STAFF REQUIREMENTS FOR HOSPITAL  
5 LICENSURE.

6 (A) REQUIREMENT.--IN ADDITION TO THE LICENSURE REQUIREMENTS  
7 SET FORTH IN SECTION 806, ALL HOSPITALS SHALL COMPLY WITH THE  
8 PROVISIONS SET FORTH IN THIS SECTION.

9 (B) RESPONSIBILITY AND AUTHORITY OF MEDICAL STAFF.--

10 (1) THE HOSPITAL SHALL HAVE AN ORGANIZED MEDICAL STAFF  
11 THAT IS DELEGATED THE RESPONSIBILITY AND AUTHORITY TO  
12 MAINTAIN AND PROMOTE PROPER STANDARDS OF MEDICAL CARE, THE  
13 QUALITY OF ALL MEDICAL CARE PROVIDED TO PATIENTS AND THE  
14 ETHICAL CONDUCT AND PROFESSIONAL PRACTICE OF ITS MEMBERS.

15 (2) THE MEDICAL STAFF SHALL BE ACCOUNTABLE TO THE  
16 HOSPITAL GOVERNING BODY FOR THE PERFORMANCE OF ITS  
17 RESPONSIBILITIES.

18 (3) THE HOSPITAL GOVERNING BODY SHALL ENSURE THAT THERE  
19 IS COMMUNICATION BETWEEN THE MEDICAL STAFF AND THE GOVERNING  
20 BODY, INCLUDING A PROCESS FOR THE MEDICAL STAFF TO  
21 PARTICIPATE IN HOSPITAL DELIBERATIONS INVOLVING MATTERS  
22 WITHIN THE SCOPE OF THE RESPONSIBILITY AND AUTHORITY  
23 DELEGATED TO THE MEDICAL STAFF.

24 (C) BYLAWS.--THE MEDICAL STAFF SHALL ADOPT, SUBJECT TO THE  
25 APPROVAL OF THE GOVERNING BODY, A SET OF BYLAWS, RULES AND  
26 REGULATIONS. THE MEDICAL STAFF SHALL DETERMINE THE METHODS FOR  
27 SELECTION, APPOINTMENT AND ELECTION OF ITS OFFICERS, INCLUDING  
28 MEMBERS OF THE MEDICAL EXECUTIVE COMMITTEE AND DEPARTMENT AND  
29 SERVICE CHAIRPERSONS.

30 (D) ORGANIZATION OF MEDICAL STAFF.--THE MEDICAL STAFF SHALL

1 BE:

2 (1) ORGANIZED TO ACCOMPLISH ITS REQUIRED FUNCTIONS,  
3 INCLUDING PROVIDING FOR THE ELECTION AND APPOINTMENT OF ITS  
4 OFFICERS. THE COMPLEXITY OF THE MEDICAL STAFF SHALL BE  
5 COMMENSURATE WITH THE SIZE OF THE HOSPITAL AND THE SCOPE OF  
6 THE ACTIVITIES OF THE MEDICAL STAFF.

7 (2) RESPONSIBLE FOR ITS OWN ORGANIZATION AND  
8 ADMINISTRATION AND SHALL PERFORM ALL SIGNIFICANT DUTIES  
9 PERTAINING THERETO. EVERY MEMBER OF THE ACTIVE MEDICAL STAFF  
10 SHALL BE ELIGIBLE TO VOTE AT STAFF MEETINGS AND TO HOLD  
11 OFFICE.

12 (E) MEDICAL STAFF MEMBERSHIP.--

13 (1) THE MEDICAL STAFF SHALL BE LIMITED TO PHYSICIANS,  
14 DENTISTS AND PODIATRISTS WHO HAVE MADE APPLICATION IN  
15 ACCORDANCE WITH THE BYLAWS, RULES AND REGULATIONS OF THE  
16 MEDICAL STAFF AND THE BYLAWS OF THE HOSPITAL.

17 (2) THE MEDICAL STAFF SHALL DETERMINE IN ITS BYLAWS THE  
18 QUALIFICATIONS AND OTHER REQUIREMENTS FOR MEDICAL STAFF  
19 MEMBERSHIP.

20 (3) MEMBERS OF THE MEDICAL STAFF SHALL CURRENTLY HOLD  
21 LICENSES TO PRACTICE IN THIS COMMONWEALTH.

22 (F) CLINICAL PRIVILEGES.--

23 (1) THE GOVERNING BODY OF THE HOSPITAL MAY GRANT  
24 CLINICAL PRIVILEGES TO QUALIFIED PRACTITIONERS IN ACCORDANCE  
25 WITH THE MEDICAL STAFF BYLAWS AND THE PRACTITIONERS'  
26 TRAINING, EXPERIENCE AND DEMONSTRATED COMPETENCE AND  
27 JUDGMENT.

28 (2) ANY PERSON GRANTED CLINICAL PRIVILEGES SHALL  
29 CURRENTLY HOLD A LICENSE TO PRACTICE IN THIS COMMONWEALTH AND  
30 ACT WITHIN THE SCOPE OF THE LICENSE, THE REQUIREMENTS OF THE

1 MEDICAL STAFF BYLAWS AND PRIVILEGE DELINEATION.

2 (3) A MEMBER OF THE MEDICAL STAFF SHALL HAVE THE  
3 ULTIMATE RESPONSIBILITY FOR THE MEDICAL CARE OF EACH PATIENT.

4 (G) DUE PROCESS.--

5 (1) THE MEDICAL STAFF SHALL DETERMINE IN ITS BYLAWS THE  
6 APPROPRIATE DUE PROCESS PROCEDURES FOR THE GRANTING,  
7 CURTAILING, SUSPENDING AND REVOKING OF MEDICAL STAFF  
8 MEMBERSHIP AND CLINICAL PRIVILEGES.

9 (2) THESE PROCESSES SHALL PROVIDE FOR THE GOVERNING BODY  
10 TO CONSIDER A RECOMMENDATION FROM THE MEDICAL STAFF BEFORE  
11 TAKING ACTION.

12 (H) ANESTHESIA.--ANESTHESIA CARE SHALL BE PROVIDED BY A  
13 QUALIFIED PHYSICIAN, ANESTHESIOLOGIST, RESIDENT PHYSICIAN-IN-  
14 TRAINING, DENTIST ANESTHETIST, QUALIFIED NURSE ANESTHETIST UNDER  
15 THE SUPERVISION OF THE OPERATING PHYSICIAN OR ANESTHESIOLOGIST  
16 OR SUPERVISED NURSE TRAINEES ENROLLED IN A COURSE APPROVED BY  
17 THE AMERICAN ASSOCIATION OF NURSE ANESTHETISTS.

18 (I) PROOF OF COMPLIANCE.--

19 (1) COMPLIANCE WITH THE PROVISIONS OF THIS SECTION MAY  
20 BE DEMONSTRATED BY THE SUBMISSION OF DOCUMENTATION OF  
21 COMPLIANCE ACCOMPANIED BY A SWORN STATEMENT SIGNED BY THE  
22 HOSPITAL CHIEF EXECUTIVE OFFICER, WHICH SHALL BE PROVIDED TO  
23 THE ACCREDITING ORGANIZATION OR THE DEPARTMENT, WHICHEVER  
24 SHALL APPLY, NO LESS THAN 30 DAYS PRIOR TO THE CURRENT  
25 LICENSE TERMINATION DATE.

26 (2) IN THE EVENT THAT A COMPLAINT ALLEGING THE  
27 HOSPITAL'S NONCOMPLIANCE WITH THIS SECTION IS RECEIVED BY THE  
28 DEPARTMENT, THE DEPARTMENT MAY CONDUCT AN ON-SITE INSPECTION,  
29 NOTWITHSTANDING THE SUBMISSION OF THE SWORN STATEMENT  
30 PERMITTED ABOVE.

SECTION 4. SECTIONS 809 AND 810(A) OF THE ACT, AMENDED  
DECEMBER 18, 1992 (P.L.1602, NO.179), ARE AMENDED TO READ:  
SECTION 809. TERM AND CONTENT OF LICENSE.

(A) CONTENTS.--ALL LICENSES ISSUED BY THE DEPARTMENT UNDER  
THIS CHAPTER SHALL:

(1) BE ISSUED FOR A SPECIFIED LENGTH OF TIME AS FOLLOWS,  
INCLUDING THE PROVISION OF SECTION 804(B):

(I) ALL HEALTH CARE FACILITIES OTHER THAN HOSPITALS  
FOR A PERIOD OF ONE YEAR[, AND FOR HOSPITALS FOR A PERIOD  
OF TWO YEARS] WITH THE EXPIRATION DATE TO BE THE LAST DAY  
OF THE MONTH IN WHICH LICENSE IS ISSUED;

(II) PROVISIONAL LICENSES FOR THE LENGTH OF TIME TO  
BE DETERMINED BY THE DEPARTMENT UPON ISSUANCE OF THE  
PROVISIONAL LICENSE;

(III) ALL ACCREDITED HOSPITALS FOR THE DURATION OF  
THE ACCREDITATION CYCLE IN GOOD STANDING WITH THE  
EXPIRATION DATE TO BE THE LAST DAY OF THE MONTH IN WHICH  
THE LICENSE IS ISSUED; AND

(IV) ALL NONACCREDITED HOSPITALS FOR A PERIOD OF  
THREE YEARS, WITH THE EXPIRATION DATE TO BE THE LAST DAY  
OF THE MONTH IN WHICH THE LICENSE IS ISSUED;

(2) BE ON A FORM PRESCRIBED BY THE DEPARTMENT;

(3) NOT BE TRANSFERABLE EXCEPT UPON PRIOR WRITTEN  
APPROVAL OF THE DEPARTMENT;

(4) BE ISSUED ONLY TO THE HEALTH CARE PROVIDER AND FOR  
THE HEALTH CARE FACILITY OR FACILITIES NAMED IN THE  
APPLICATION;

(5) SPECIFY THE MAXIMUM NUMBER OF BEDS, IF ANY, TO BE  
USED FOR THE CARE OF PATIENTS IN THE FACILITY AT ANY ONE  
TIME; AND

(6) SPECIFY LIMITATIONS WHICH HAVE BEEN PLACED ON THE FACILITY.

(B) POSTING.--THE LICENSE SHALL AT ALL TIMES BE POSTED IN A CONSPICUOUS PLACE ON THE PROVIDER'S PREMISES.

(C) VISITATION.--WHENEVER PRACTICABLE, THE DEPARTMENT SHALL MAKE ITS VISITATIONS AND OTHER REVIEWS NECESSARY FOR LICENSURE CONTEMPORANEOUSLY WITH SIMILAR VISITATIONS AND OTHER REVIEWS NECESSARY FOR PROVIDER CERTIFICATION IN THE MEDICARE AND MEDICAL ASSISTANCE PROGRAMS AND THE DEPARTMENT SHALL ENDEAVOR TO AVOID DUPLICATION OF EFFORT BY THE DEPARTMENT AND PROVIDERS IN THE CERTIFICATE OF NEED, MEDICAL ASSISTANCE AND MEDICARE PROVIDER CERTIFICATION AND LICENSURE PROCEDURES. THIS SHALL NOT PRECLUDE THE DEPARTMENT FROM UNANNOUNCED VISITS.

(D) USE OF BEDS IN EXCESS OF MAXIMUM.--EXCEPT IN CASE OF [EXTREME EMERGENCY] NATURAL DISASTERS, CATASTROPHES, ACTS OF BIO-TERRORISM, EPIDEMICS OR OTHER EMERGENCIES, NO LICENSE SHALL PERMIT THE USE OF BEDS FOR INPATIENT USE IN THE LICENSED FACILITY IN EXCESS OF THE MAXIMUM NUMBER SET FORTH IN THE LICENSE WITHOUT FIRST OBTAINING WRITTEN PERMISSION FROM THE DEPARTMENT: PROVIDED, THAT DURING THE PERIOD OF A LICENSE, A HEALTH CARE FACILITY MAY WITHOUT THE PRIOR APPROVAL OF THE DEPARTMENT INCREASE THE TOTAL NUMBER OF BEDS BY NOT MORE THAN TEN BEDS OR 10% OF THE TOTAL BED CAPACITY, WHICHEVER IS LESS.

SECTION 810. RELIANCE ON ACCREDITING AGENCIES AND FEDERAL GOVERNMENT FOR HEALTH CARE FACILITIES OTHER THAN HOSPITALS.

(A) REPORTS OF OTHER AGENCIES.--AFTER A PROVIDER HAS BEEN LICENSED OR APPROVED TO OPERATE A HEALTH CARE FACILITY OTHER THAN A HOSPITAL FOR AT LEAST TWO YEARS UNDER THIS OR PRIOR ACTS, NONE OF WHICH HAS BEEN PURSUANT TO A PROVISIONAL LICENSE, THE

1 DEPARTMENT MAY RELY ON THE REPORTS OF THE FEDERAL GOVERNMENT OR  
2 NATIONALLY RECOGNIZED ACCREDITING AGENCIES TO THE EXTENT THOSE  
3 STANDARDS ARE DETERMINED BY THE DEPARTMENT TO BE SIMILAR TO  
4 REGULATIONS OF THE DEPARTMENT AND IF THE PROVIDER AGREES TO:

5 (1) DIRECT THE AGENCY OR GOVERNMENT TO PROVIDE A COPY OF  
6 ITS FINDINGS TO THE DEPARTMENT; AND

7 (2) PERMIT THE DEPARTMENT TO INSPECT THOSE AREAS OR  
8 PROGRAMS OF THE HEALTH CARE FACILITY NOT COVERED BY THE  
9 AGENCY OR GOVERNMENT INSPECTION OR WHERE THE AGENCY OR  
10 GOVERNMENT REPORT DISCLOSES MORE THAN A MINIMAL VIOLATION OF  
11 DEPARTMENT REGULATIONS.

12 \* \* \*

13 SECTION 5. THE ACT IS AMENDED BY ADDING A SECTION TO READ:  
14 SECTION 810.1. RELIANCE ON NATIONAL ACCREDITATION ORGANIZATIONS  
15 FOR HOSPITALS.

16 (A) REPORT OF OTHER AGENCIES.--AFTER A PROVIDER HAS BEEN  
17 LICENSED OR APPROVED TO OPERATE A HOSPITAL FOR AT LEAST THREE  
18 YEARS UNDER THIS OR A PRIOR ACT, NO PORTION OF WHICH HAS BEEN  
19 PURSUANT TO A PROVISIONAL OR OTHER RESTRICTED LICENSE, IF  
20 REQUESTED BY THE FACILITY, THE DEPARTMENT SHALL RELY ON THE  
21 REPORT OF AN ACCEPTABLE ACCREDITATION ORGANIZATION AUTHORIZED  
22 PURSUANT TO THIS SECTION AND SECTION 806.

23 (B) APPLICATION AND APPROVAL PROCESS.--AN ACCREDITATION  
24 ORGANIZATION SHALL APPLY TO THE DEPARTMENT FOR APPROVAL. PRIOR  
25 TO APPROVAL, THE DEPARTMENT SHALL:

26 (1) DETERMINE THAT THE STANDARDS OF THE ACCREDITATION  
27 ORGANIZATION ARE EQUAL TO OR MORE STRINGENT THAN EXISTING  
28 LICENSURE SURVEY REQUIREMENTS;

29 (2) EVALUATE THE SURVEY OR INSPECTION PROCESS OF THE  
30 ACCREDITATION ORGANIZATION TO ENSURE THE INTEGRITY OF THE

1 SURVEY OR INSPECTION PROCESS; AND

2 (3) ENTER INTO A WRITTEN AGREEMENT WITH THE  
3 ACCREDITATION ORGANIZATION THAT INCLUDES REQUIREMENTS FOR:

4 (I) NOTICE OF ALL SURVEYS AND INSPECTIONS;

5 (II) SHARING OF COMPLAINTS AND OTHER RELEVANT  
6 INFORMATION;

7 (III) PARTICIPATION OF THE DEPARTMENT IN  
8 ACCREDITATION ORGANIZATION ACTIVITIES;

9 (IV) PROTECTION OF THE CONFIDENTIALITY OF MEDICAL  
10 AND PERSONAL RECORDS; AND

11 (V) ANY OTHER PROVISION NECESSARY TO ENSURE THE  
12 INTEGRITY OF THE ACCREDITATION AND LICENSURE PROCESS.

13 (C) FINDING OF SUBSTANTIAL COMPLIANCE OF HOSPITAL.--

14 (1) WHEN AN APPROVED ACCREDITATION ORGANIZATION HAS  
15 ISSUED A FINAL REPORT FINDING A HOSPITAL TO BE IN SUBSTANTIAL  
16 COMPLIANCE WITH THE ACCREDITATION ORGANIZATION'S STANDARDS,  
17 THE DEPARTMENT SHALL ACCEPT THE REPORT AS EVIDENCE THAT THE  
18 HOSPITAL HAS MET THE DEPARTMENT'S LICENSURE REQUIREMENTS AND  
19 SHALL GRANT THE HOSPITAL DEEMED STATUS. THE FINAL REPORT MUST  
20 HAVE BEEN ISSUED NO MORE THAN ONE YEAR PRIOR TO THE  
21 EXPIRATION DATE OF THE HOSPITAL'S LICENSE.

22 (2) A HOSPITAL THAT RECEIVES A CONDITIONAL  
23 ACCREDITATION, PROVISIONAL ACCREDITATION, PRELIMINARY OR  
24 FINAL DENIAL OF ACCREDITATION SHALL BE SUBJECT TO FULL  
25 LICENSURE SURVEY BY THE DEPARTMENT.

26 (D) REPORTS TO DEPARTMENT.--

27 (1) AN APPROVED ACCREDITATION ORGANIZATION SHALL SEND  
28 THE DEPARTMENT ALL FINAL ACCREDITATION REPORTS OF EACH  
29 INSPECTION AND SURVEY AT THE TIME IT IS SENT TO THE HOSPITAL.

30 (2) A FINAL REPORT OF AN APPROVED ACCREDITATION

1 ORGANIZATION SHALL BE MADE IMMEDIATELY AVAILABLE TO THE  
2 PUBLIC IN ACCORDANCE WITH DEPARTMENT PRACTICE.

3 (3) A PRELIMINARY OR FINAL REPORT OF AN APPROVED  
4 ACCREDITATION ORGANIZATION IS NOT ADMISSIBLE AS EVIDENCE IN  
5 ANY CIVIL ACTION OR PROCEEDING.

6 (E) INSPECTIONS BY DEPARTMENT.--THE DEPARTMENT MAY INSPECT  
7 AN ACCREDITED HOSPITAL TO:

8 (1) FOLLOW UP ON ANY SYSTEMIC CONCERNS OR EVENTS  
9 IDENTIFIED BY AN APPROVED ACCREDITATION ORGANIZATION OR BY  
10 REPORTS FILED BY THE FACILITY;

11 (2) INVESTIGATE A COMPLAINT;

12 (3) VALIDATE THE FINDINGS OF AN APPROVED ACCREDITATION  
13 ORGANIZATION THAT DETERMINED THAT A HOSPITAL IS IN COMPLIANCE  
14 WITH CONDITIONS OF PARTICIPATION ISSUED BY THE CENTERS FOR  
15 MEDICARE AND MEDICAID SERVICES AND STATE LICENSURE  
16 REQUIREMENTS; OR

17 (4) COMPLY WITH THE REQUEST OF ANY FEDERAL OR STATE  
18 REGULATORY ENTITY.

19 (F) PARTICIPATION OR OBSERVATION OF SURVEYS OR INSPECTIONS  
20 BY ACCREDITATION ORGANIZATION BY THE DEPARTMENT.--THE DEPARTMENT  
21 MAY PARTICIPATE IN OR OBSERVE A SURVEY OR INSPECTION OF A  
22 HOSPITAL CONDUCTED BY AN APPROVED ACCREDITATION ORGANIZATION.

23 (G) ACTIONS BY THE DEPARTMENT ON ACCREDITATION  
24 ORGANIZATION'S FAILURE TO MEET OBLIGATIONS.--

25 (1) UPON DETERMINATION BY THE DEPARTMENT THAT AN  
26 APPROVED ACCREDITATION ORGANIZATION HAS FAILED TO MEET ITS  
27 OBLIGATIONS UNDER THIS SECTION, THE DEPARTMENT SHALL HAVE 30  
28 DAYS FROM THE TIME IT NOTIFIES THE ACCREDITATION ORGANIZATION  
29 TO RESOLVE ANY ISSUES THAT ARE RESULTING IN THE ACCREDITING  
30 AGENCY'S NOT MEETING ITS OBLIGATIONS.



1       (2) IF, AFTER 30 DAYS, THE DEPARTMENT AND THE  
2       ACCREDITING ORGANIZATION HAVE NOT REACHED AN AGREEMENT THAT  
3       BRINGS THE ACCREDITING ORGANIZATION BACK INTO COMPLIANCE WITH  
4       THIS ACT, THE DEPARTMENT SHALL PROVIDE NOTICE IN THE  
5       PENNSYLVANIA BULLETIN THAT IT INTENDS TO TAKE ACTION TO  
6       WITHDRAW THE APPROVAL OF THE ACCREDITATION ORGANIZATION, LIST  
7       THE REASONS THIS ACTION IS BEING TAKEN, MAKE AVAILABLE THE  
8       ACCREDITATION ORGANIZATION'S RESPONSE TO THE DEPARTMENT AND  
9       RECEIVE PUBLIC COMMENT REGARDING THIS DECISION FOR A PERIOD  
10      OF NOT LESS THAN 30 DAYS.

11      (3) IF, AFTER THE CONCLUSION OF THE PUBLIC COMMENT  
12      PERIOD, THE DEPARTMENT'S DETERMINATION IS THAT THE APPROVED  
13      ACCREDITATION ORGANIZATION HAS FAILED TO MEET ITS OBLIGATION  
14      UNDER THIS SECTION, THE DEPARTMENT MAY WITHDRAW APPROVAL OF  
15      THE ACCREDITATION ORGANIZATION GRANTED UNDER SECTIONS 806 AND  
16      810 AND IMMEDIATELY TERMINATE THE AGREEMENT BETWEEN THE  
17      DEPARTMENT AND THE ACCREDITATION ORGANIZATION.

18      (4) ANY HOSPITAL THAT HAS ACHIEVED DEEMED STATUS AS A  
19      RESULT OF BEING ACCREDITED BY THE ACCREDITATION ORGANIZATION  
20      TERMINATED BY THE DEPARTMENT SHALL KEEP THE DEEMED STATUS  
21      UNTIL THE END OF THE CURRENT LICENSURE PERIOD. TO RENEW A  
22      LICENSE, THE HOSPITAL SHALL EITHER BE ACCREDITED BY ANOTHER  
23      DEPARTMENT-APPROVED ACCREDITATION ORGANIZATION OR SHALL BE  
24      SUBJECT TO THE DEPARTMENT'S LICENSURE REGULATIONS AS PROVIDED  
25      FOR IN SECTION 806(I) (5).

26      SECTION 6. THIS ACT SHALL TAKE EFFECT IN 180 DAYS.