

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 AND WATSON,  
MAY 23, 2011

REFERRED TO COMMITTEE ON HEALTH, MAY 23, 2011

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, for licensure,  
11 for term and content of license and for reliance on  
12 accrediting agencies and Federal Government.

13 The General Assembly of the Commonwealth of Pennsylvania  
14 hereby enacts as follows:

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

20 Section 802.1. Definitions.

21 The following words and phrases when used in this chapter  
22 shall have, unless the context clearly indicates otherwise, the

1 meanings given them in this section:

2 \* \* \*

3 "Health care facility." [For purposes of Chapter 8, a health  
4 care facility includes, but is not limited to, a general,  
5 chronic disease or other type of hospital, a home health care  
6 agency, a home care agency, a hospice, a long-term care nursing  
7 facility, cancer treatment centers using radiation therapy on an  
8 ambulatory basis, an ambulatory surgical facility, a birth  
9 center regardless of whether such health care facility is  
10 operated for profit, nonprofit or by an agency of the  
11 Commonwealth or local government. The department shall have the  
12 authority to license other health care facilities as may be  
13 necessary due to emergence of new modes of health care. When the  
14 department so finds, it shall publish its intention to license a  
15 particular type of health care facility in the Pennsylvania  
16 Bulletin in accordance with the act of June 25, 1982 (P.L.633,  
17 No.181), known as the "Regulatory Review Act." The term health  
18 care facility shall not include an office used primarily for the  
19 private practice of a health care practitioner, nor a program  
20 which renders treatment or care for drug or alcohol abuse or  
21 dependence unless located within a health facility, nor a  
22 facility providing treatment solely on the basis of prayer or  
23 spiritual means. The term health care facility shall not apply  
24 to a facility which is conducted by a religious organization for  
25 the purpose of providing health care services exclusively to  
26 clergymen or other persons in a religious profession who are  
27 members of a religious denomination.] For the purposes of this  
28 act, the term shall include hospitals, cancer treatment centers  
29 using radiation therapy on an ambulatory basis, ambulatory  
30 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.

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

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

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

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

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

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

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

29       (A) A list of operative procedures proposed to  
30 be performed at the facility and the ages of the

1           patients to be served.

2           (B) The type of anesthetic proposed to be used  
3           for each operative procedure.

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

7           (D) Other information the department deems  
8           necessary for registration.

9           (2) A license shall be obtained to operate a  
10          freestanding Class B or Class C ASF.

11          (3) An ASF license shall designate the licensed facility  
12          as either a Class B or Class C ASF.

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

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

19               (ii) The highest level of anesthetic proposed to be  
20               used for each proposed operative procedure.

21               (iii) The highest physical status proposed to  
22               receive ambulatory surgery at the facility.

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

27          (5) If a facility desires to change its classification  
28          level from a Class B enterprise to a Class C enterprise, the  
29          facility shall request and obtain a license prior to  
30          providing services to patients with a physical status of ASF

1 Class III or level III.

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

7 (7) Criteria for ambulatory surgery:

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

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

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

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

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

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

28 (vii) The practitioner performing the surgery is  
29 responsible for obtaining the informed consent of the  
30 patient for disclosure to the patient of the risks,

1 benefits and alternatives associated with the anesthesia  
2 which will be administered, the procedure that will be  
3 performed and the comparative risks, benefits and  
4 alternatives to performance of the procedure in the ASF.

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

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

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

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

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

28 (3) Anesthesia services shall be provided by an  
29 anesthesiologist who is a graduate of an anesthesiology  
30 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

1 medical technology.

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

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

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

19 (1) The care of patients.

20 (2) The medical supervision of patients.

21 (3) The physical environment.

22 (4) Infection control.

23 (5) Quality assurance.

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

26 (7) Sanitation.

27 (8) Safety.

28 (9) Dietary matters.

29 (c) Fire and emergency standards.--Notwithstanding any other  
30 provision of law other than standards required for Federal

certification by that type of health care facility in the Medicare or Medicaid program[, no]:

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

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

\* \* \*

Section 3. Sections 809(a) and (d) 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 accredited health care facilities [other than hospitals for a period of one year, and for hospitals for a period of two years], for the duration of 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.

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

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

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

18 \* \* \*

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