



REPORT OF THE QUALITY ASSURANCE PROGRAMS

July 1, 2012 - June 30, 2013

Final report completed December 16, 2013

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Introduction

The Department of Health administers the Health Care Facilities Act of 1979 [P.L. 130, No. 48]. Section 448.804(d) of the Act requires an annual report to the General Assembly on the effectiveness of the licensing under Chapter 8 of the Act. Health care facility licensing actions are carried out through the Bureaus of Facility Licensure Certification and Community Program Licensure and Certification. The act defines health care facilities as: ambulatory surgical facilities, general hospitals, special hospitals, long term care nursing facilities, birth centers, home health care agencies and cancer treatment centers. A 1999 amendment to the Act added hospices and in 2006 the Act was amended to require the Department to license home care agencies and home care registries. In 2011, abortion facilities were included as ambulatory surgical facilities.

This report contains information on the issuance of licenses to health care facilities and on the status of the Department's efforts to license facilities through the survey process. The report also includes information describing additional quality assurance functions of the Department. All statistical data displayed in the charts are collected in the Quality Assurance Survey Agency Information System (SAIS), which serves as the infrastructure for all QA survey and certification activities.

Survey and Certification Program

In addition to surveying, licensing and certifying facilities to ensure that state quality and safety standards are met, the Department performs quality assurance functions for the federal Medicare and Medicaid programs, also to assure basic levels of quality and safety are met by healthcare providers.

The Department maintains a staff of 203 knowledgeable and trained surveyors (Health Facility Quality Examiners) who inspect for compliance with all the major quality and safety requirements that are specified in regulation. Most are registered nurses; however, to ensure a comprehensive survey process, teams are augmented with surveyors who are psychologists, nutritionists, social workers and occupational or speech therapists.

The Department and the Medicare and Medicaid agencies work together to ensure that appropriate remedies are promptly applied and implemented effectively when evidence indicates that these standards are not being met.

The Department and the federal Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) provide for regular, ongoing training for all surveyors to ensure they maintain current knowledge and thorough understanding of state and federal healthcare facility regulations/conditions of participation and proper use of required data gathering and reporting systems.

The Department conducts health and life safety surveys according to timeframes established by state and federal regulations. In addition, the Department conducts occupancy and verification surveys and is responsible for responding to complaints, which often require on-site or off-site surveys, depending on the nature of the complaint.

The Department investigates all complaints regarding care rendered by licensed health care facilities and registered agencies. Complaints are received from various sources including the Department's website, hotline calls through 1-800-254-5164, calls and written correspondence directed to the Central Office/Field Office, referrals from other agencies, Governor's Hotline, Attorney General's Office, legislators' offices, or emails submitted to a designated complaint email address. If the issue identified in the complaint is not under the jurisdiction of the Division, referrals are made to other Department offices, other state agencies or local authorities as appropriate.

All complaint investigations are reviewed. If the nature of the complaint indicates residents or patients could be seriously impacted by the circumstances, it is investigated immediately. Upon completion of the investigation, the division or field office responsible for investigating the complaint informs the complainant of the investigation. If the investigation reveals that the facility or agency is not in compliance with any state or federal regulations, a deficiency citation is issued and the facility/agency is required to submit a plan of correction to the Department for review and approval. The Department reviews the facility's compliance to determine if the deficient practice has been corrected.

The following pages provide descriptive information on each facility type and 2012-2013 survey and complaint data. In addition, information is provided about sanctions as defined in PA Code §51.54.

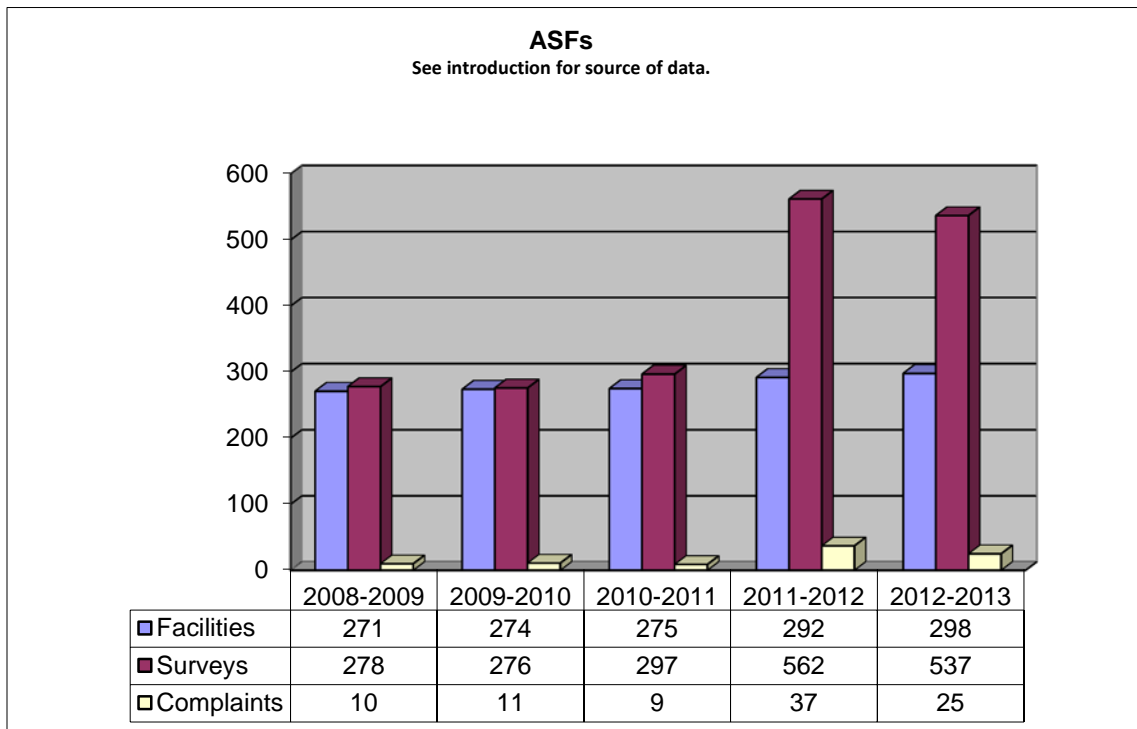
Ambulatory Surgical Facilities

There were 298 Ambulatory Surgical Facilities (ASFs) licensed in Pennsylvania as of June 30, 2013. That number is an increase of 6 facilities over the previous SFY (State Fiscal Year). In SFY 2012-13, 9 initial licenses were issued and 10 ASFs changed ownership.

Ambulatory surgical facilities (ASF) are classified as A, B, or C based on procedures performed, patient status, and anesthesia used. Class A facilities register annually with the Department, but are not licensed. Class B and C ASFs are licensed on an annual basis through an announced on-site survey. If found to be out of compliance with the licensure regulations, ASFs must develop and submit plans of correction in response to the identified deficiencies, for review and acceptance by the Division of Acute and Ambulatory Care (DAAC). ASFs are subject to revisits to determine if the facility has achieved compliance through implementation of an acceptable plan of correction.

The Department received and investigated 25 complaints related to ASFs during the report period. In addition, 328 licensure/certification surveys, 37 occupancy surveys and 147 revisits were conducted for ASFs in SFY 2012-13, representing a decrease of 8 licensure/certification surveys and 9 occupancy surveys and an increase of 4 revisits over prior SFY.

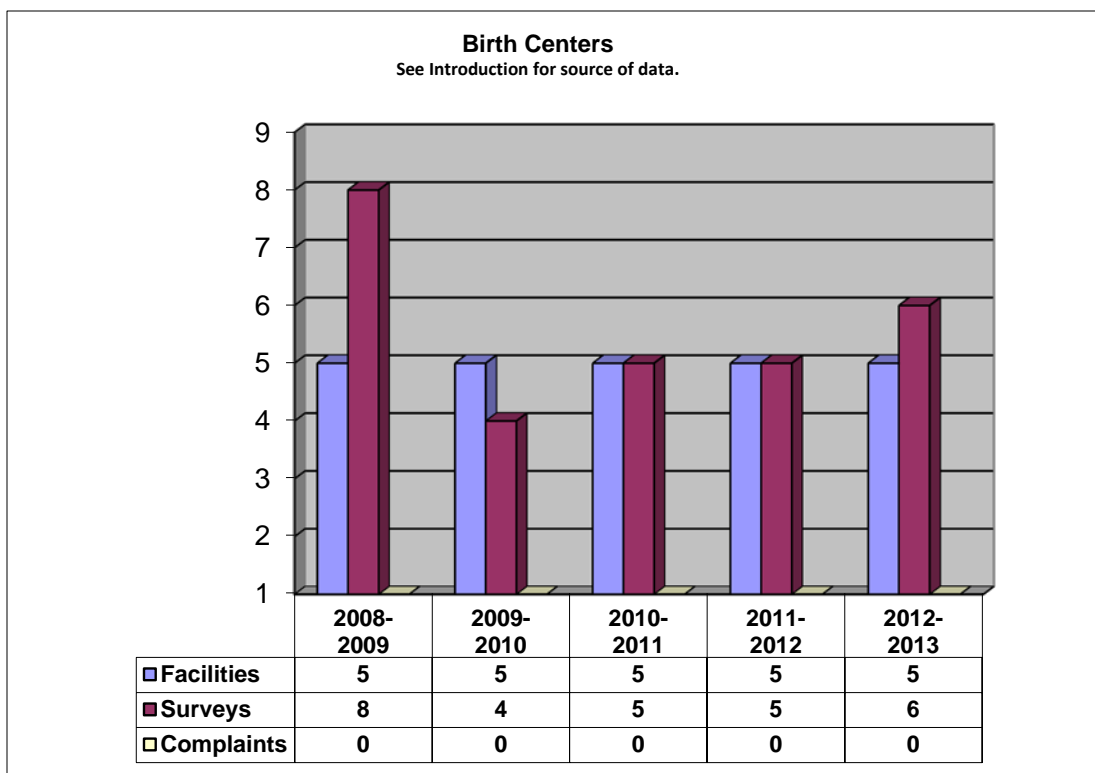
The number of ASFs, surveys and complaints over the last five years are displayed in the following chart. Additional information about serious events and infrastructure failures reported by ASFs is provided on pages 14-15.



Birth Centers

There are five licensed birth centers in the Commonwealth. Birth center licensure surveys are conducted on-site annually. All centers surveyed were found to be in compliance with licensure requirements. The Department received no complaints regarding the care and services provided by birth centers during this reporting period and the preceding four years.

The number of Birth Centers, surveys and complaints over the last five years are displayed in the following chart. Additional information about serious events and infrastructure failures reported by Birth Centers is provided on pages 14-15.



Home Health Agencies

All home health agencies (HHA) that provide intermittent skilled nursing services and at least one other therapeutic service must be licensed by the Commonwealth. Licensure requires a survey. HHAs choosing to participate in the Medicare program must also be certified as eligible. The Department conducts certification activities, which include surveying and complaint investigation, for the federal government. Qualified nurse surveyors conduct both state licensure surveys and federal certification surveys.

During this reporting period, there were 463 HHAs operating in the Commonwealth, a decrease of 3 agencies from the previous reporting period.

The Department certified 416 HHAs to allow them to receive Medicare reimbursement from CMS. These 416 HHAs also required a state license. The remaining 47 HHAs are only state licensed because they choose not to participate in the federal reimbursement programs. The Department conducted 197 Medicare and/or state licensure on-site surveys in SFY 2012-13.

All Medicare certified HHAs must comply with federal regulations, which require an on-site survey conducted within a 36-month period. The Department also conducts on-site surveys on an additional five percent targeted sample selected from a CMS list that identifies those agencies most at risk of providing poor care. Additionally, validation surveys are conducted on five percent of deemed agencies. Agencies with the best compliance records are surveyed on-site every three years. Medicare surveys include home visits to patients by the state surveyor to observe and evaluate the quality of care provided by the agency. All on-site surveys are unannounced.

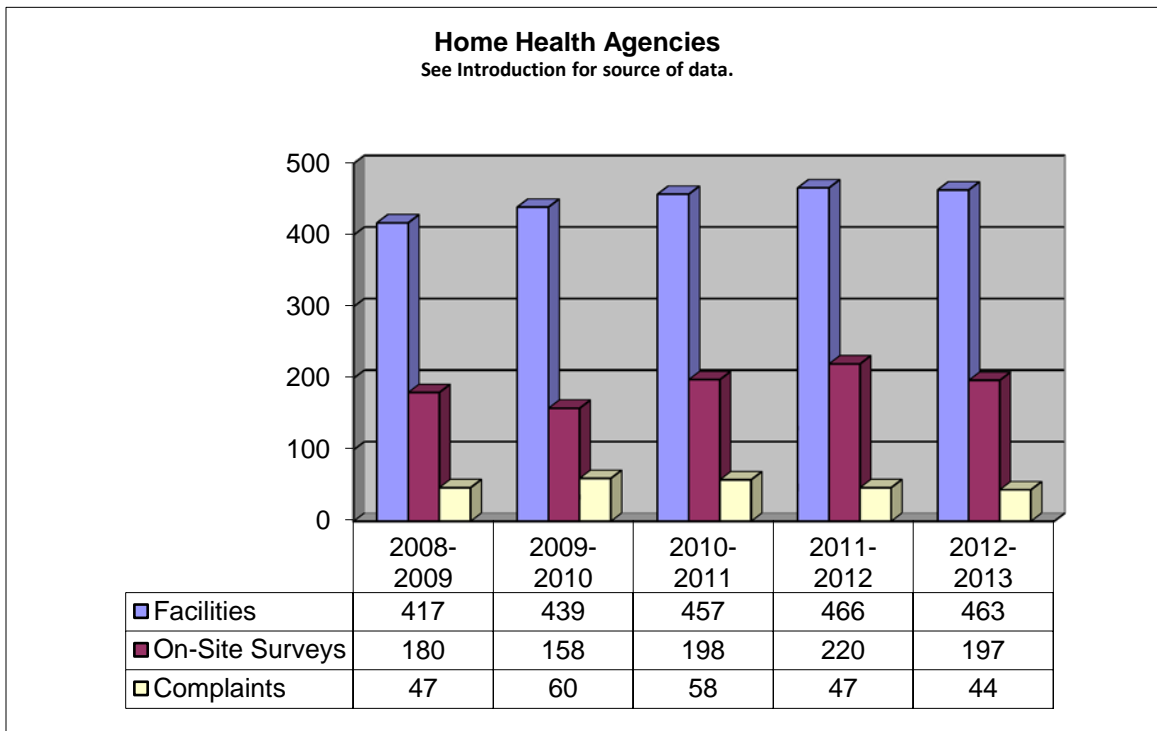
In order to coordinate the federal 36-month survey time frame with the state requirement for annual licensure surveys, off-site surveys are conducted for state licensure purposes. An off-site survey is based on written documentation of compliance with licensure requirements, attested to by the agency administrator as correct and submitted to the Department.

During SFY 2012-13, the survey schedule was changed from 2 on-site and 1 written (off-site) surveys in a 3 year period to 1 onsite survey and 2 written surveys conducted in 3 years. This survey schedule is consistent with state and federal home health care survey requirements and was necessary to accommodate a decrease in surveyor staff.

Forty four (44) HHA complaints were received and investigated, a decrease of three complaint investigations from the previous reporting period. Of the 44 complaints investigated, 17 were substantiated. None of the allegations in any of the complaints identified conditions that were considered to pose a threat of immediate jeopardy to the health and safety of patients.

In response to home health care providers' concerns about the requirement for physician's countersignature within 7 days of an oral order, the Department issued surveyor guidelines permitting flexibility within 28 Pa. Code §601.31—"Acceptance of Patients, Plan of Treatment and Medical Supervision. (d) Conformance with Physician Order". The department's guidelines outline specific conditions under which a home health agency may be exempt from the requirement to obtain the physician's countersignature within 7 days.

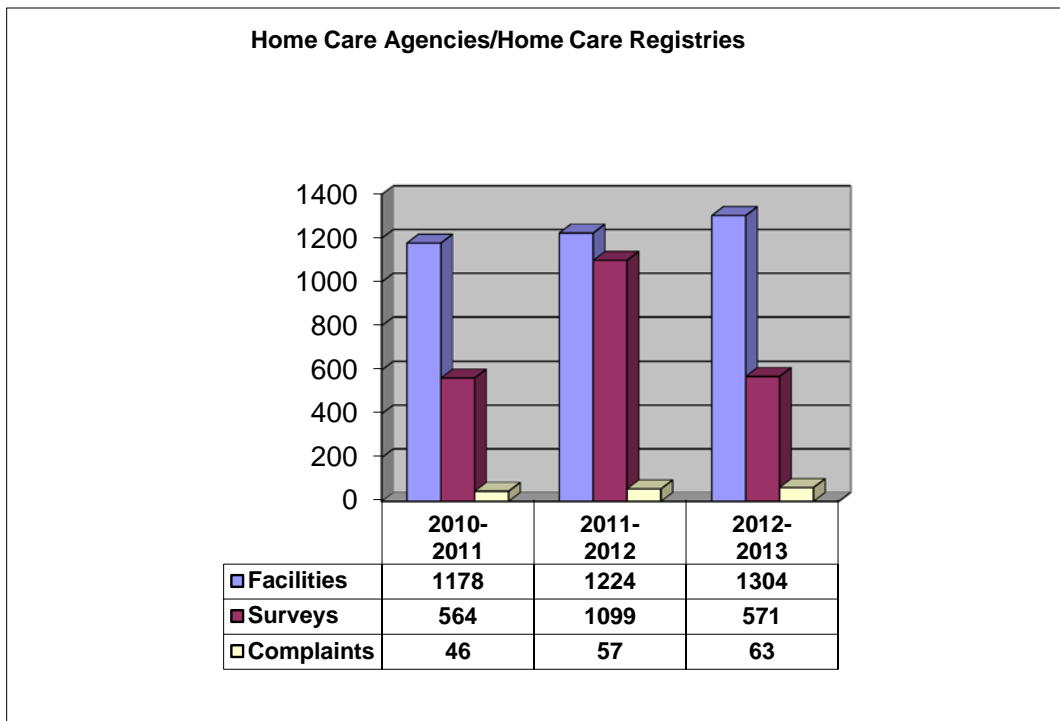
The number of HHAs, surveys and complaints over the last five years are displayed in the following chart.



Home Care Agencies

Home Care Agencies and Home Care Registries provide non-skilled services to individuals in their homes or other independent living environments.

Licensure regulations for home care agencies and registries became effective in December, 2009. Over a three year period the number of agencies and registries has grown from 1178 to 1304, an 11% increase. The number of agencies, surveys conducted and complaints received for the past three years are displayed in the following chart.



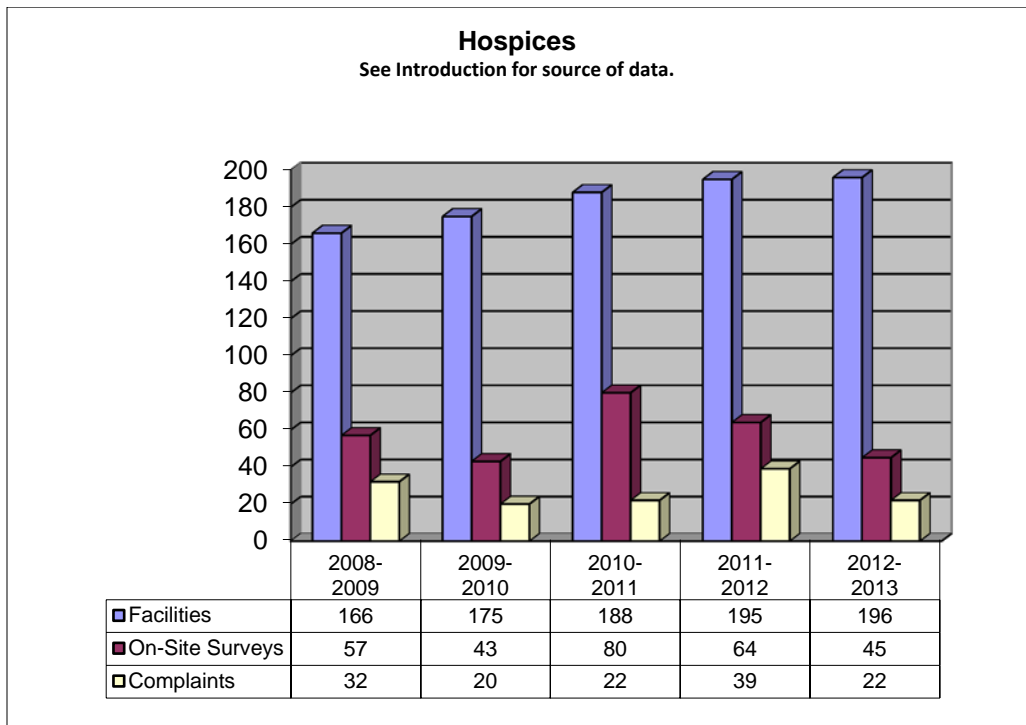
Hospices

The Department currently uses Medicare standards to license hospices. One hundred ninety six (196) hospices are licensed and Medicare certified. This is an increase of one hospice agencies from the previous reporting period. Currently no hospices are state licensed only.

Hospices are surveyed by on-site and off-site methods. On average, 33% of all licensed hospices are surveyed on-site annually. This varies contingent upon the number of on-site Medicare recertification surveys required for the given year. An off-site survey is based on written documentation of compliance with licensure requirements, attested to by the agency administrator as correct and submitted to the Department for review. In SFY 2012-13, the Department surveyed 45 facilities on-site and 151 were licensed through off-site surveys.

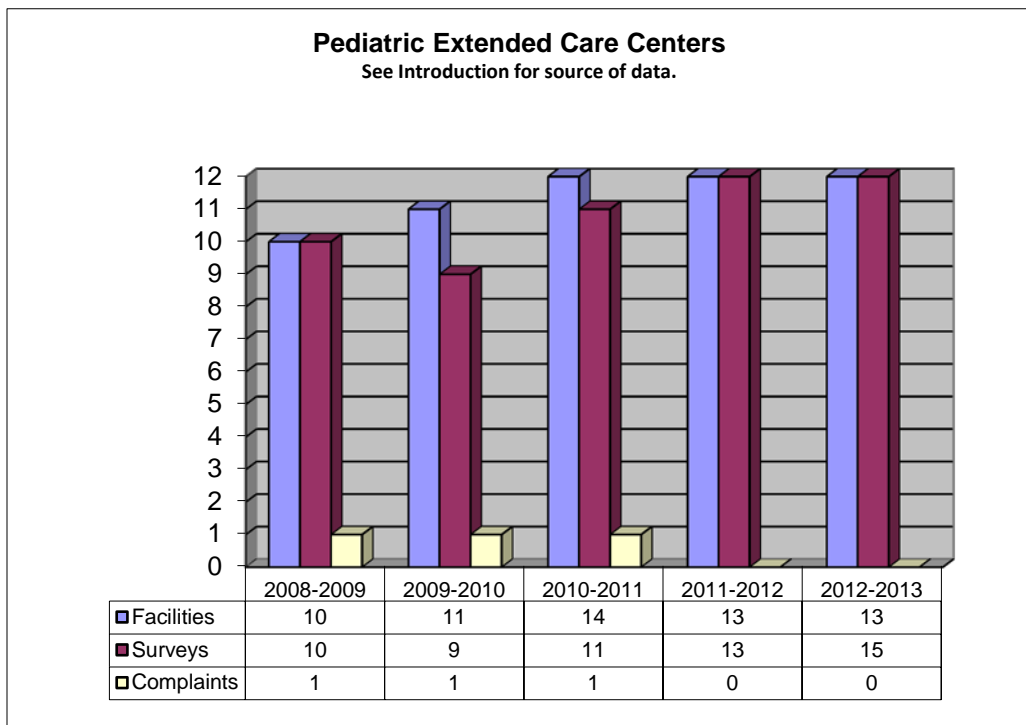
During SFY 2012-13, 22 hospice complaints were investigated. Of the 22 complaints investigated, six were substantiated. All providers with substantiated complaints submitted acceptable plans of correction and no sanctions were imposed.

The number of hospices, on-site surveys conducted and complaints received for the past five years are displayed in the following chart:



Pediatric Extended Care Centers

A Pediatric Extended Care Center (PECC) is a non-residential childcare facility staffed by nurses and therapists who provide day care and clinical intervention to medically dependent or technologically dependent children. PECCs do not provide 24-hour care and the children do not stay overnight. Their goal is to provide comprehensive and coordinated care to benefit families and to realize a significant cost saving. Communication with the child's physician allows for the appropriate medical care and intervention while the child is at the PECC, up to 12 hours in each 24-hour period. Act 11 of 2012 increased the PECC service eligibility age from 8 to 21 years old. PECCs are licensed annually using an unannounced on-site survey. During the SFY 2012-13 reporting period, there were 13 PECC facilities licensed in the Commonwealth. The Department received no complaints regarding the care and services provided by these PECCs.



Hospitals

The Department conducts state licensure surveys of general acute care hospitals, long-term acute care hospitals, and specialty hospitals. The Department does not license federal VA Medical Centers or psychiatric hospitals, which are licensed by the Department of Public Welfare.

As of June 30, 2013, the Department licensed 155 acute care hospitals, 19 rehabilitation hospitals, 6 children's hospitals, 26 long-term acute care hospitals, and

13 critical access hospitals. The total number of licensed acute care facilities was 219.

A regular hospital license is issued for two years. Beginning in January, 2014, the licensure period will be extended to three years. (See Act 60 of 2013) The hospital licensure process begins with the scheduling of an announced on-site survey based on the licensure cycle. During SFY 2012-13, the Department issued 101 hospital licenses. Licensure surveys are required for regular state licensure, bed decreases and increases, additions of or reductions in services, occupancy surveys, complaint and event investigations, facility closures, changes of ownership, changes of name and mergers. The Department completed 142 surveys during SFY 2012-13.

When deficient practices are identified during inspection and investigation activities, the facility is required by the Department to develop and submit a plan of correction. Unannounced revisits are used to assess facility success in implementing and monitoring the plan of correction and compliance with licensure regulations. In SFY 2012-13, the Department completed 351 revisits, an increase of 19 revisits over the prior SFY.

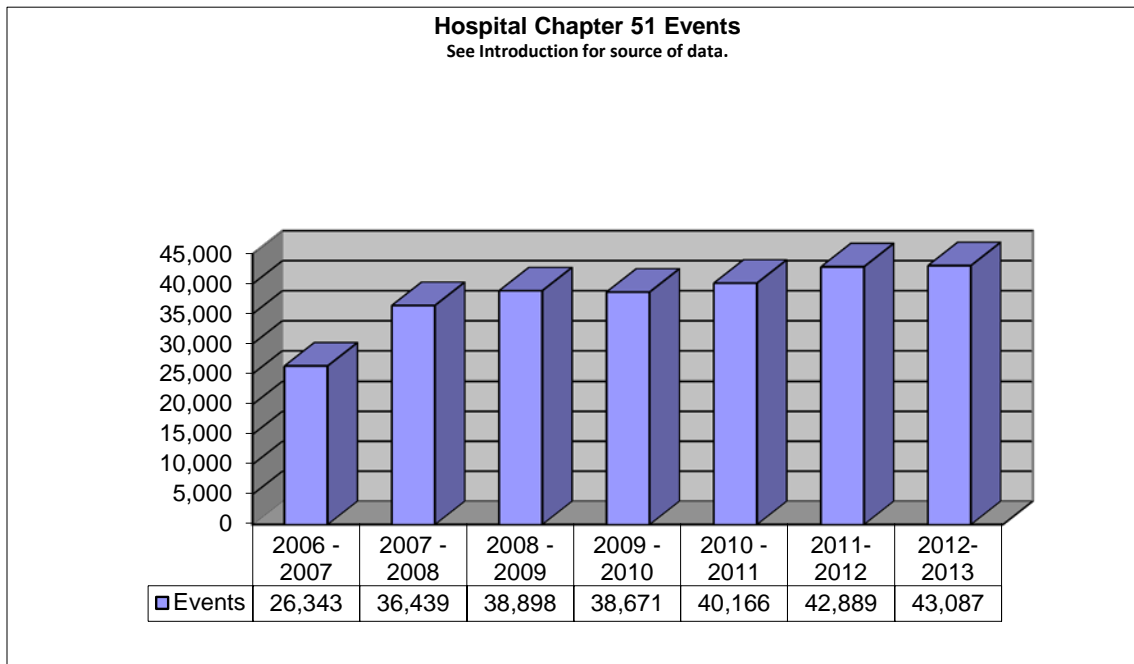
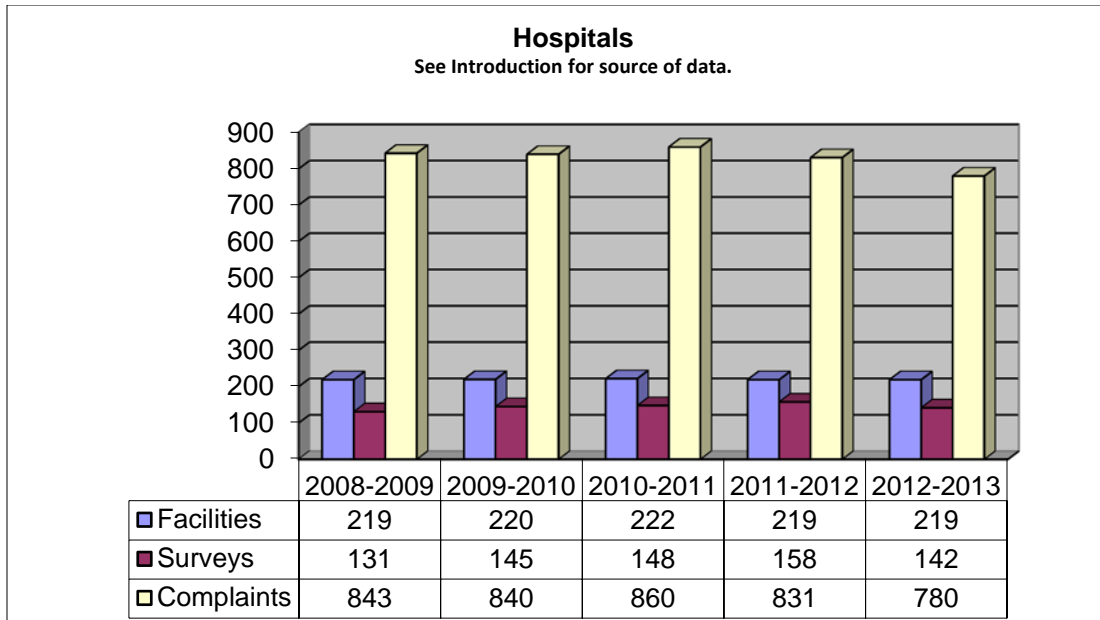
Beginning in January 2014, the Department will permit approved accreditation organization surveys to be used in lieu of state licensure surveys for hospitals only. The choice must be made by the facility. The surveys are conducted to the standards developed by the accreditation organization unless state law standards are stricter, in which case the state law standards shall apply.

Before a hospital may offer services to the public, the facility must be inspected by the Department and approved for new services and/or the use of new or renovated space. Two types of surveys are required, one to assess the physical plant (life safety) and the other to assess the clinical program. The Department conducted 682 program occupancy surveys in SFY 2012-13 for new services and/or new or renovated sites in hospitals, a decrease of 168 surveys over the prior SFY.

The Department received a total of 780 complaints related to hospitals during this reporting period, a decrease of 51 complaints over the prior SFY. All complaints are thoroughly investigated. If an on-site investigation of a complaint is warranted, the investigation is unannounced.

In addition to complaints, the Department tracks events reported by hospitals in compliance with parts of Chapter 51 of the Health Care Facilities Regulations.

The numbers of licensed hospitals, surveys, and complaints are displayed in the following charts.



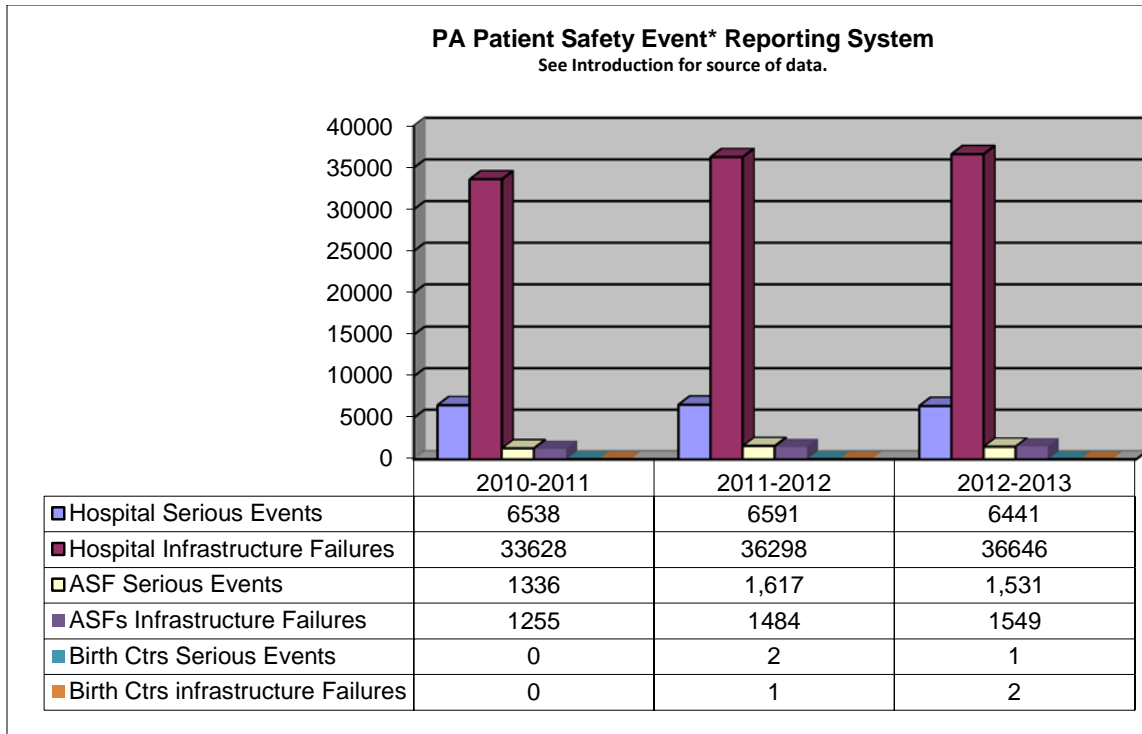
*Chapter 51 events are situations or occurrences at a facility that could seriously compromise quality assurance or patient safety

Patient Safety Activities and Reporting

Act 13 of 2002 delegated specific responsibilities for the Department in implementing the Patient Safety Act. Review and approval of the Patient Safety Plans for newly licensed facilities is included as part of the initial survey procedure. Implementation of the plans by licensed facilities is assessed during routine re-licensure surveys as well as during complaint and/or event investigations.

As required by the Act, the Department of Health collects the annual surcharge based on a per unit (bed, procedure or operating room) assessment set by the PSA. Hospitals (including private psychiatric hospitals), ambulatory surgical facilities, birthing centers, and abortion providers performing 100 or more procedures per year are subject to the assessment. The surcharge receipts are placed in the Patient Safety Authority trust fund for use in the collection and analysis of patient safety information, and no portion of these funds may be retained by the Department. In SFY 2012-2013, the amount of \$6,417,863.90 was billed and collected.

The Department also reviews and responds to patient safety data reported by facilities in the PA Patient Safety Event Reporting System (PA PSERS). During FY 2012-13, 2,922 serious events and infrastructure failures were reported by ASFs to the Department of Health, an increase of 329 from the prior year. Hospitals reported 40,926 serious events and infrastructure failures, an increase of 760 reports over the prior year. All serious events and infrastructure failure reports are reviewed by division staff and onsite investigations are conducted as required. Hospital, ASF and birth center specific data for the past three years are reported in the following charts.



***Serious events** are events, occurrences or situations involving the clinical care of a patient in a medical facility that either: a) results in death, or b) compromises patient safety *and* results in an unanticipated injury requiring the delivery of additional health care services to the patient.

Infrastructure failures are: a) undesirable or unintended events, occurrences or situations that affect the infrastructure (i.e., physical plant and service delivery systems) of a medical facility, or b) the discontinuation or significant disruption of a service which could seriously compromise patient safety.

Nursing Care Facilities

As of June 30, 2013, there were 710 nursing homes licensed in Pennsylvania, housing 88,492 long-term care beds. These facilities are surveyed for yearly licensure on a variable schedule. All on-site surveys for licensure, follow-up, complaint, incident and abuse are unannounced. Medicare certification surveys, conducted for CMS, are also unannounced and are scheduled during a 15 month window dating from the previous Medicare certification survey. When possible, Medicare certifications and state licensure surveys are conducted concurrently to minimize impact on the nursing home and for operational efficiency. In addition to nursing care facility licensure surveys, the Department performs occupancy surveys. These occupancy surveys for new facilities or renovated spaces in existing facilities are conducted after a Life Safety Code occupancy inspection and prior to use of the area for patient care. The Department conducted 180 occupancy surveys of nursing care facilities during the fiscal year.

Category	Surveys Completed
Licensure/Certifications	716
License Only	4
Certification Only	22
Initial Certification	0
Complaints	1,777

See Introduction for source of data.

All complaints are investigated. Eighty-five percent of complaints were investigated on-site. If multiple complaints are received simultaneously, they may be investigated during the same survey for added efficiency. Although the majority of complaints are investigated through on-site visits, off-site complaint investigations are also conducted if appropriate for issues not affecting resident care, such as billing, or problems already identified by surveyors that the facility is in the process of correcting.

During SFY 2012-13, the Department conducted 1,002 follow-up visits to ensure the facilities corrected deficiencies and demonstrated compliance with all regulations. The most frequent deficient practices cited during SFY 2012-13 were: 1) maintaining residents at their highest practicable level 2) infection control 3) supervision and assistance to prevent accidents 4) documentation of clinical records and 5) sanitary food preparation, serving and storage.

The Department conducts “monitoring visits” at facilities that have received ten or more complaints. These are unannounced visits and are performed when a surveyor is in the vicinity of one of the designated nursing homes. This is a time-efficient device for the Department and enables more frequent spot-checks to monitor the progress of high risk facilities.

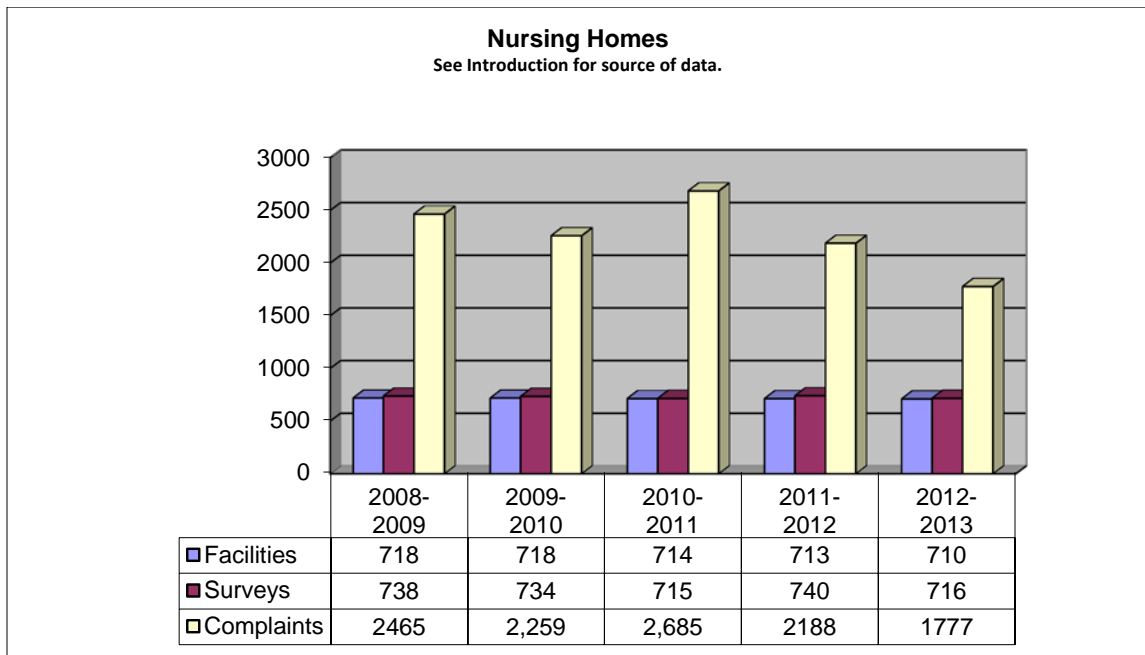
The federal government provides states with Titles XVIII and XIX grant awards to assist with funding of nursing home initiatives. To meet these initiatives, the Department conducts 10% of surveys during evenings, weekends and nights and also enhanced monitoring for poor-performing nursing homes. The monitoring includes on-site semi-annual certification, monthly monitoring visits, and complaint investigations. Additional nursing home initiatives include: monitoring of facilities that are experiencing fiscal difficulty (bankruptcy) and altering the survey protocols to include using quality indicators and enhanced investigative protocols for weight loss, dehydration, and pressure sores; assessing a facility’s abuse prevention procedures; and investigating residents who are receiving drugs considered dangerous to the geriatric population.

From July 1, 2012 through June 30, 2013, the Department received and investigated 1,777 complaints. The complaint process has enhanced the level of surveillance in facilities with histories of poor care as evidenced by high numbers of complaints. The increased frequency of visits in poorly performing facilities enables the Department to recommend more timely sanctions to CMS, as well as provide evidence supporting stringent state sanctions.

In addition to complaints, the Department tracks events that are reported by nursing homes. Nursing homes report events in accordance with the PA Code, Chapter 51 through a mandatory web-based electronic event report system (ERS). The system is designed to give facilities the ability to generate reports on their facility's reported events for use in process improvement efforts and outcome monitoring.

Division survey staff review event reports and, based upon assessment of the actual or potential effect on patient health and safety, determine the need for immediate on-site investigation or integration into other survey activities. Analysis of the data helps to identify trends affecting patient safety, to improve patient safety and to focus future survey activity. During SFY 2012-13, 20,027 events were reported. Submitted incidents are reviewed and additional on-site investigation visits are conducted if necessary.

The number of facilities, surveys and complaints for the past five years are displayed in the chart below:



Nurse Aide Registry

The Nurse Aide Registry is federally mandated. The purpose of this registry is to ensure the safety and wellbeing of nursing home residents across the state, and to assure other state registries are aware of annotated nurse aides in Pennsylvania. The Department maintains the state's registry which currently lists 276,797 total nurse aides, 100,165 of whom are active. Inactive nurse aides are individuals whose registration has lapsed and those with substantiated findings of abuse, neglect, or misappropriation of resident property.

Safety Inspection

During SFY 2012-13, the Department performed 1,431 Life Safety Code surveys and 874 Life Safety Code revisits for Hospitals, ASFs, Nursing Care Facilities, Birth Centers, Intermediate Care Facilities, ESRDs (Dialysis Centers), Hospices, PECCs Six new Medicare validation surveys and six Medicare validation monitoring revisit surveys were done.

The Department also performed two new Fire Safety Evaluation System (FSES) surveys. All surveys to verify compliance, or substantial compliance in the case of nursing homes, are unannounced. An exception to this can be given for Non-LTC facilities, other than HHAs, which meet the criteria listed in Section 2700A of the State Operations Manual.

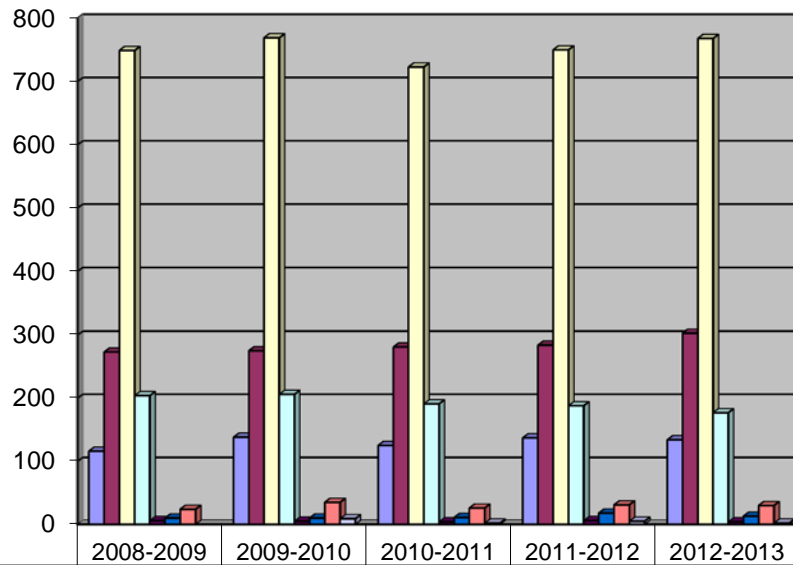
The Department also reviewed 2,834 plans for construction or renovation of health care facilities. Of these plans, 1,770 met safety standards and were approved. These projects represent over \$1.54 billion in construction costs. Plan reviewers are qualified by the Civil Service Commission based on their education and experience.

Prior to use or occupancy of a newly constructed facility or a renovated space, the Department performs a Life Safety Code occupancy inspection. During SFY 2012-13, the Department's Division of Safety Inspection staff performed 1,130 occupancy inspections and 200 preoccupancy surveys.

The Department's Safety Inspection staff conducted 3,647 surveys during SFY 2012-13. The number of surveys by facility type for the past five years is displayed in the following graph.

Life Safety Code Surveys

See Introduction for source of data.



	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013
Hospitals	116	138	125	137	134
ASFs	273	275	281	284	303
Nursing Homes	749	769	723	750	768
ICF/IIDs	204	206	191	188	177
Birth Centers	6	5	4	6	4
PECCs	10	10	11	18	13
Hospices	24	35	26	31	30
ESRDs		9	2	5	2

ENFORCEMENT ACTIONS

The Department is authorized by PA Code §51.41 and, in collaboration with CMS, to sanction health care facilities that do not rectify violations. Each facility is required to develop and submit a Plan of Correction (POC) that addresses violations identified by health or life safety surveys. In the event that a facility fails to submit an acceptable POC or, upon a follow up survey is found to continue to be in violation of health or life safety standards, the Department sanctions the facility.

The Department may use state Civil Monetary Penalty funds to place temporary managers in facilities as a supportive measure to assist the facility to achieve and maintain compliance or to assist in the orderly transfer of residents for the purpose of closure.

Sanctions during this reporting period are described below.

Termination Actions

ICF/ID 90-day termination actions: 5

Provisional Licenses Issued:

ASF: 1

Hospital: 1 (recommendation to DPW which licenses this unit)

Home Health Agencies: 1

Home Care Agencies: 5

Hospices: 2

Nursing Care Facilities: 4

Temporary Managers Placed: 2

ADDITIONAL QUALITY ASSURANCE ACTIVITIES

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/ID) and Psychiatric Residential Treatment Facilities (PRTF)

The Department ensures the health, safety and welfare of residents in 177 intermediate care facilities for individuals with intellectual and developmental disabilities (ICF/ID), and individuals with other related conditions (ICFs/ORC). The legal authority for the Department's regulatory activities is derived from Title XIX of the Social Security Act, Articles IX and X of the Public Welfare Code, and the Life Safety Code. The Department has similar oversight of 93 psychiatric residential treatment facilities for individuals under age 21 (PRTFs). Both facility types are inspected for compliance with federal certification standards through regular unannounced recertification, post-certification and monitoring surveys. These surveys are conducted according to federal protocol.

The Department investigates complaints and unusual occurrences that impact the health, safety and welfare of the individuals living in ICFs and PRTFs. Some of these pertain to abuse, neglect, mistreatment, substandard care, misappropriation of funds, and other related health and safety issues. On-site investigations of complaints, which impact on resident health or safety, are a high priority.

The Department provides the ICF survey certification outcome information for the federal programs under Title XIX to the Department of Aging and Department of Public Welfare Office of Long Term Living. The Department also provides the certification information to the Department of Public Welfare, Office of Developmental Programs, for licensure purposes. In addition, the Department provides the Bureau of Program Integrity, Department of Public Welfare with the survey certification outcome for the PRTFs.

End Stage Renal Disease (ESRD)

The ESRD program oversees annual Medicare recertification of 279 renal dialysis centers. Each center is recertified every 3 years. In FY 2012-13, 4 centers denied recertification because of noncompliance with Medicare Conditions of Participation.

Managed Care

The Bureau of Managed Care reviews, approves, licenses and monitors the quality of care provided to consumers by health maintenance organizations (HMOs) and other managed care systems. Total HMO enrollment for the second quarter of 2013 was 3,454,707, which is a 5.1% increase when compared to the same quarter in 2012.

Managed care plans in Pennsylvania that provide services to public sector clients, such as CHIP and HealthChoices, show continued enrollment growth: Aetna Better Health (+9.9%), HealthAmerica of PA (+77%), UMPC For You (+35.5%), and Vista Health Plan (+10.4%). In addition, two companies – Today's Options and Humana – have submitted applications for a certificate of authority to offer a Medicare HMO starting in January 2014.

Healthcare Associated Infection Prevention

The Healthcare Associated Infection Prevention (HAIP) Section was established to execute the Department of Health's responsibilities created by Act 52 of 2007. HAIP monitors and validates healthcare associated infection data entered by hospitals into a national database and provides hospitals with regular data validation reports that identify actual and potential reporting errors or missing data, with a 30 day period for the hospital to correct or verify the data. Formal data analysis and rate calculation are done periodically. On-site data reporting audits, funded in 2010 and 2011 through an Epidemiology and Laboratory Capacity (ELC) grant from the Centers for Disease Control and Prevention, and on-site educational visits implemented in 2011 to review the hospital's achievement in implementing the requirements of Chapter 4 of The Medical Care Availability and Reduction of Error (MCARE) Act, 40 P.S. §§ 1303.401-1303.411 were discontinued due to a reduction in funding and staff compliment. Instead, outreach telephone calls and web collaboration were used to educate hospital infection prevention staff on the requirements of Act 52 of 2007 and the new criteria released by the CDC in January of 2013.

Nursing homes began reporting healthcare associated infections into Pennsylvania-Patient Safety Reporting System (PA-PSRS) in June, 2009. The Department reviews this data and provides individual facility data integrity and validation reports to allow each facility to correct problems that may exist with their data and to help facilities assure that the information regarding infections reported to PA-PSRS is accurate and dependable.

Drug, Device, and Cosmetic (DDC) Program

The DDC program oversees several drug and medical device laws. This oversight includes registration and compliance of Pennsylvania-based manufacturers, distributors, and retailers of any drugs, medical devices and equipment, medical gases, and medicated cosmetics. Licensure is specific to human prescription drug or medical gas distributors. The program is also responsible for administrative duties related to the scheduling and handling of controlled substances and List I chemicals. The program often partners with other federal and state agencies regarding the integrity of the United States drug supply. Consumer complaints regarding retail sales of medical devices and nonprescription drugs are investigated and handled as well.

Drug Device and Cosmetic Program Current Registrants

Type	No. of registrants
Manufacturer (Prescription)	487
Manufacturer (Non-Prescription)	79
Distributor (Prescription)	1058
Distributor (Non-Prescription)	421
Retailer (Non-Prescription)	7606
Devices	2725
Wholesaler/Distributor Licenses	744

Hearing Aid Program

The Hearing Aid program is responsible for oversight of the Pennsylvania Hearing Aid Sales Registration Law and Regulations. This responsibility includes the registration and compliance of Pennsylvania's professional fitters, apprentices, and temporary fitters as well as hearing aid dealers/sellers. The program qualifies new hearing aid fitters through the administration of a semi-annual examination. There is also limited oversight of audiologists and physicians who sell or distribute hearing aids. Consumer complaints regarding sales of hearing aids are investigated and handled as well.

Hearing Aid Program Active Registrants

Type	Registrants
Fitters	488
Dealers	466
Apprentices	68
Branches – Dealer	534
Branches – Fitter	0
TOTAL	1556

CRITICAL ISSUES

Percutaneous Coronary Intervention (PCI) Exception Committee Procedure

The Department's hospital regulations (28 Pa. Code Chapter 138) include provisions regarding the performance of cardiac catheterization procedures. Cardiac catheterizations are categorized as either low risk or high risk. High risk cardiac catheterizations are those that present a high risk of significant cardiac complication. PA Code §138.15 (relating to high-risk cardiac catheterizations) provides that a hospital may perform high risk cardiac catheterizations only if it has an open heart surgical program onsite. Included in this category are percutaneous coronary interventions (PCI), which are an important group of technologies for the diagnosis and treatment of patients with cardiovascular disease.

In response to hospitals' requests for exceptions to this regulation and the need to ensure access to PCI for citizens in rural areas, the department permitted a limited number of facilities without onsite open heart surgery capacity to offer PCI under an agreement that included specific detailed requirements intended to assure patient safety and required reporting to the National Cardiovascular Data Registry (NCDR). In addition, the department required facilities to enroll in a nationally recognized research project known as C-PORT conducted by Johns Hopkins University.

Currently, 17 Pennsylvania facilities without onsite cardiac surgery are permitted by exception to offer elective PCI. The Department is using the NCDR reports to monitor outcomes.

During FY 2012-13 the department conducted an extensive review of national research findings and outcome study data, PHC4 PCI data, and outcome data the department collected in August, 2012. The department also reviewed current national PCI guidelines and practice standards as well as regulatory approaches to PCI taken by other state governments. Based on findings of this extensive review of relevant clinical research, current clinical standards and regulatory practices, the department developed a draft discussion paper for stakeholder review.

Telemedicine

In response to the growing use of telemedicine as a strategy for delivering healthcare, and the absence of facility regulations specific to telemedicine services, the department developed Telemedicine Guidelines and Department of Health Survey Policy. The document's primary purpose is to provide guidance to department surveyors, incorporating the optimal standards of care based on current knowledge of telemedicine technology. It also educates hospitals about survey requirements for telemedicine services.

Act 60

Act 60 was signed into law by Governor Corbett on July 5, 2013. The bill amended the Health Care Facilities Act by authorizing the department to rely on hospital surveys/inspections conducted by nationally recognized accreditation organizations in lieu of the department's licensure surveys. The Act also extends the term of licensure from two years to three years for all hospitals.

During FY 2012-13 the department developed an Act 60 implementation plan to prepare for this change to licensure by "deeming". The department initiated discussion and negotiation with federally recognized hospital accreditation agencies to develop agreements under which they will conduct surveys for compliance with state laws and hospital regulations as well as their own accreditation standards, including standards and procedures for reporting survey findings to the department.

The department engaged in extensive discussion with facilities and the hospital association and outlined administrative procedures for internal implementation of the changes brought about by Act 60, including plans for ongoing communications with stakeholders.

NEW ITEMS

Department of Health/Patient Safety Authority Data Summit

Consistent with the legislative intent of the MCARE Act, the Department and the PA Patient Safety Authority initiated a collaborative project to focus on three areas of mutual concern to QA and PSA: reporting standardization, education and training, and facility reporting. Work groups were established comprised of members representing the two agencies along with representatives of the Hospital and Health System Association of PA (HAP) and the PA Ambulatory Surgery Association (PASA) who provide the perspective of hospitals and ambulatory surgery facilities. The reporting standardization work group will publish guidance to provide consistent, clear standards for MCARE reporting requirements so that the Authority, the Department and healthcare facility staff have a shared understanding of the requirements. The education and training task force will develop and implement educational activities to ensure the shared understanding, interpretation and application of these guidelines.

Expedited Exceptions Process for Hospitals

The Department finalized instructions to hospitals for expedited exceptions for five current hospital regulations and two current ASF regulations:

- 28 Pa. Code §107.2 (b) Medical Staff Membership
- 28 Pa. Code §107.62 (a,b) Oral Orders (Verbal Orders)
- 28 Pa. Code §123.25 (2) Control of Anesthetic Explosion Hazards

- 28 Pa. Code §127.32 Written Orders (Radiology Services)
- 28 Pa. Code §555.32 (a) Administration of Anesthesia
- 28 Pa. Code §551.21 (d) Criteria for Ambulatory Surgery
- 28 Pa. Code §569.35 (7) General Safety Precautions (Flammable agents in ASF)

Hospitals and ASFs seeking an expedited exception must submit specific documents that provide evidence that the hospital/ASF meets the Department's requirements for operating under that exception. The information has been transmitted to the surveyors and to HAP for further distribution. The Department is working to develop additional expedited exceptions for review by the Exceptions Committee.