



REPORT OF THE QUALITY ASSURANCE PROGRAMS

July 1, 2013 - June 30, 2014

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Introduction

The Department of Health (Department) administers the Health Care Facilities Act (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.

The information posted on the Department of Health's website is posted in accordance with requirements imposed by the Centers for Medicare and Medicaid Services (CMS). These health care facility search pages contain information regarding health care facility compliance with regulatory requirements for licensure and for certification. Licensure permits the facility to operate in Pennsylvania. Certification permits the facility to claim and receive payment for services rendered from the Medicare and Medicaid programs. The Department of Health, as state licensing agency and State Survey Agency for CMS, conducts both routine and special inspections of health care facilities to determine ongoing compliance with regulatory requirements, which are a condition of licensure and certification. If, during an inspection, the Department determines a facility does not meet all regulatory requirements for licensure and certification, the Department notifies the facility in a Statement of Deficiencies. Health care facilities are required to submit a Plan of Correction in response to the Statement of Deficiencies. The Plan of Correction is mandatory, regardless of whether the facility agrees with Department findings or not, and is the means by which the Department monitors and ensures correction of deficiencies. As long as the facility submits a Plan of Correction, the facility may continue to operate and receive Medicare and Medicaid payment while deficiencies are being corrected. A Plan of Correction, for purposes of licensure

and certification, is not an admission of wrongdoing on the part of the facility for purposes of a private lawsuit and should not be regarded as such.

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 health care providers.

The Department maintains a staff of 213 knowledgeable and trained surveyors (health facility quality examiners and safety inspectors-) who assess compliance with all the major quality and safety requirements that are specified in regulation. Most health quality surveyors 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 quality and safety 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 health care 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, validation, and monitoring 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 following pages provide descriptive information on each facility type and 2013-2014 survey and complaint data. In addition, information is provided about sanctions as defined in PA Code §51.54.

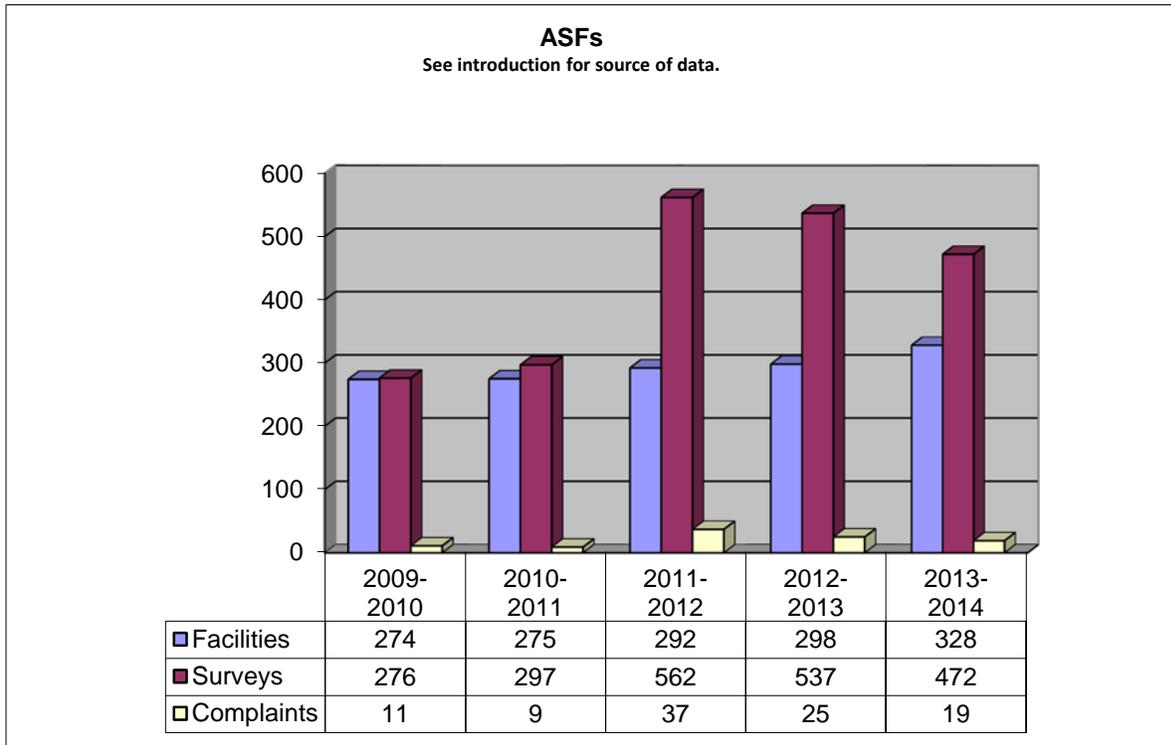
Ambulatory Surgical Facilities

There were 328 Ambulatory surgical facilities (ASFs) licensed in Pennsylvania as of June 30, 2014. That number is an increase of 30 facilities over the previous SFY (state fiscal year). In SFY 2013-14, 11 initial licenses were issued and nine 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 19 complaints related to ASFs during the report period. In addition, 346 licensure/certification surveys, 33 occupancy surveys, and 95 revisits were conducted for ASFs in SFY 2013-14, representing an increase of 18 licensure/certification surveys and a decrease of four occupancy surveys and 49 revisits over prior SFY.

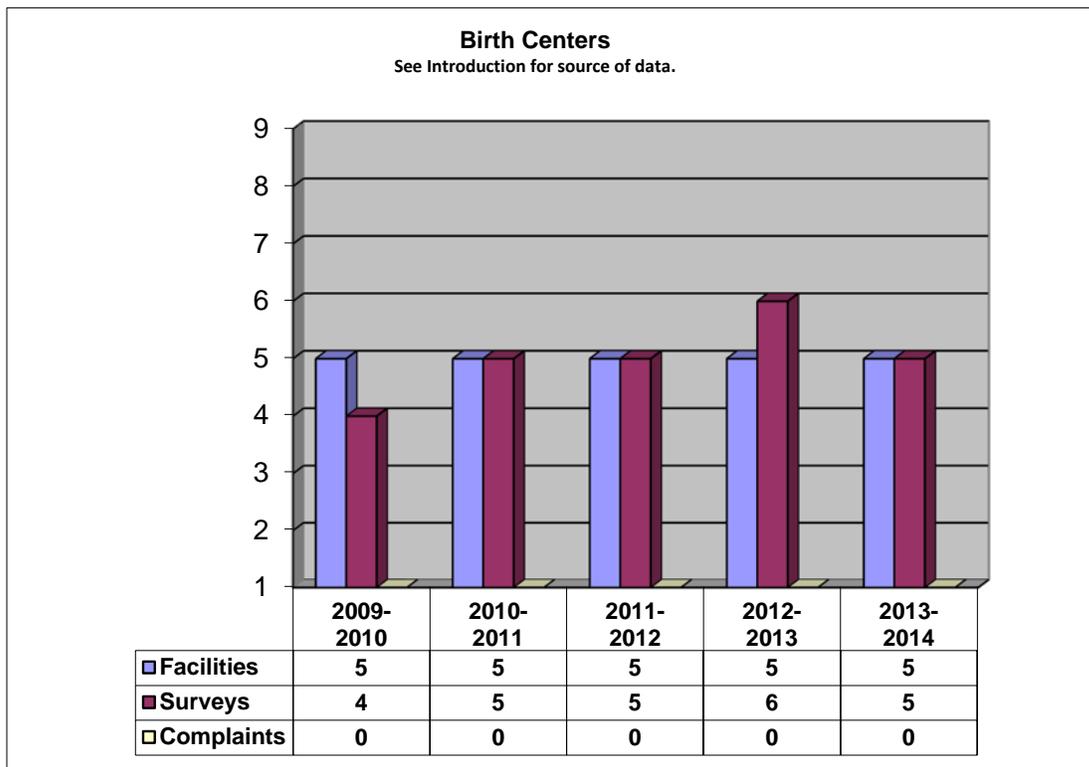
The number of ASFs, surveys, and complaints over the last five years are displayed in the following chart. Additional information about serious events and infrastructure failures reported by ASFs is provided on pages 15.



Birth Centers

There are five licensed birth centers in the commonwealth. Unannounced birth center licensure surveys are conducted on-site annually. 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 page 15.



Home Health Agencies

All home health agencies (HHA) must provide intermittent skilled nursing services and at least one other therapeutic service and 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 517 HHAs operating in the commonwealth, an increase of 54 agencies from the previous reporting period, representing slightly

greater than 10 percent annual growth in the commonwealth's home health agencies.

The Department recommended certification for 432 HHAs to allow them to receive Medicare reimbursement from CMS. These 432 HHAs also required a state license. The remaining 85 HHAs are only state licensed because they choose not to participate in the federal reimbursement programs. The Department conducted 219 Medicare and/or state licensure on-site surveys in SFY 2013-14.

All Medicare-certified HHAs must comply with federal regulations, which require an on-site survey within a 36-month period. 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. The Department also conducts on-site surveys on an additional 5 percent targeted sample of agencies that are selected based on agency performance data. Additionally, validation surveys are conducted on 5 percent of deemed agencies. Agencies with the best compliance records are surveyed on-site every three years.

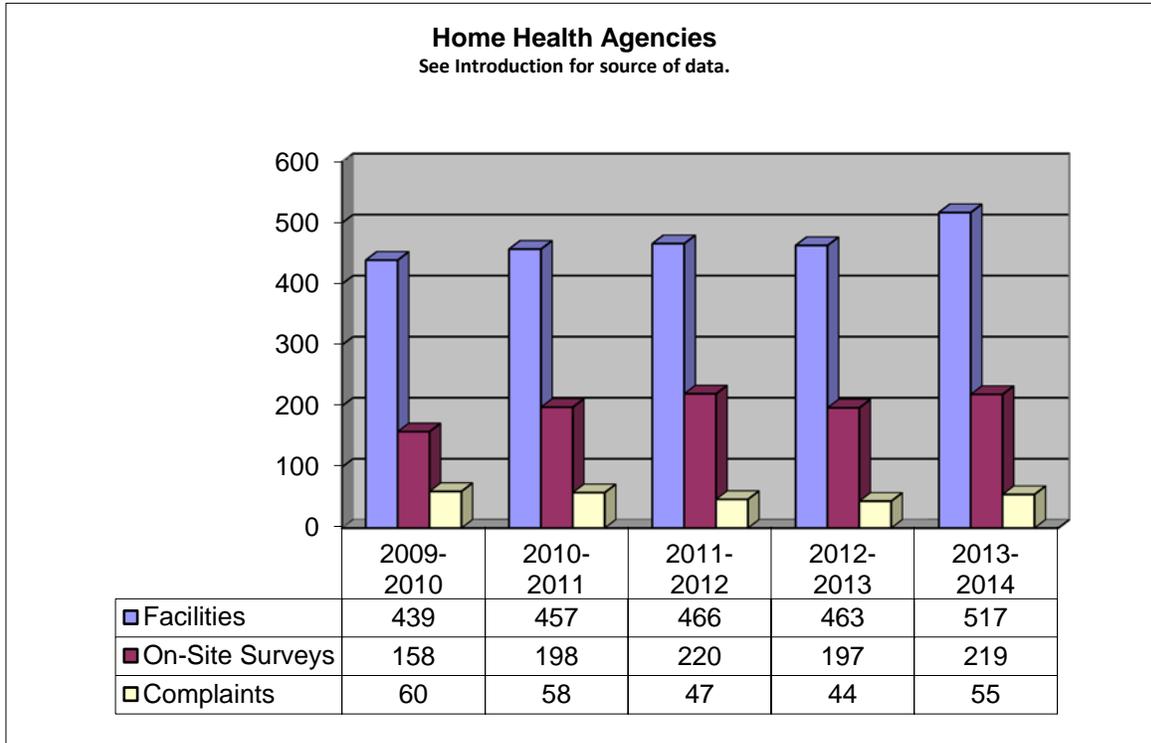
In order to coordinate the federal 36-month survey time frame with the state requirement for annual licensure surveys, off-site surveys are conducted for state licensure purposes. An off-site survey is based on written documentation of compliance with licensure requirements, attested to by the agency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

During SFY 2013-14, the home health care agencies survey schedule included one onsite survey and two written surveys conducted in a three-year period. This survey schedule is consistent with state and federal home health care survey requirements.

Fifty-five HHA complaints were received and investigated, which is an increase of 11 complaint investigations from the previous reporting period. Of the 55 complaints investigated, 14 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 or safety of patients.

In addition to complaints, the Department tracks events that are reported by Home Health Agencies through a mandatory web-based electronic event report system (ERS) in accordance with the PA Code, Chapter 51. The system is designed to give facilities the ability to generate and analyze their reported event data for use in process improvement efforts and outcome monitoring.

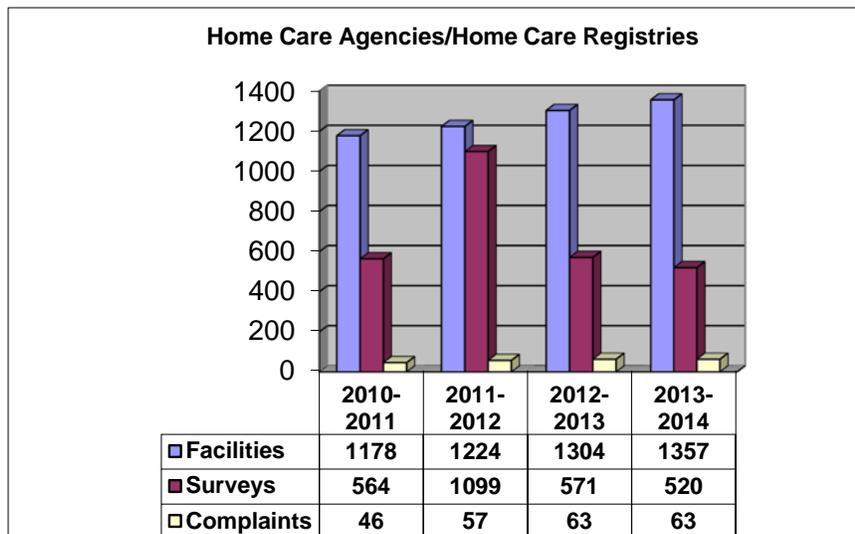
The number of HHAs, surveys and complaints over the last five years are displayed in the following chart.



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 the last year, the number of agencies and registries increased by approximately 4 percent from 1304 to 1357. The four-year growth rate for home care agencies and registries is approximately 15 percent. The number of agencies, surveys conducted, and complaints are displayed in the following chart.



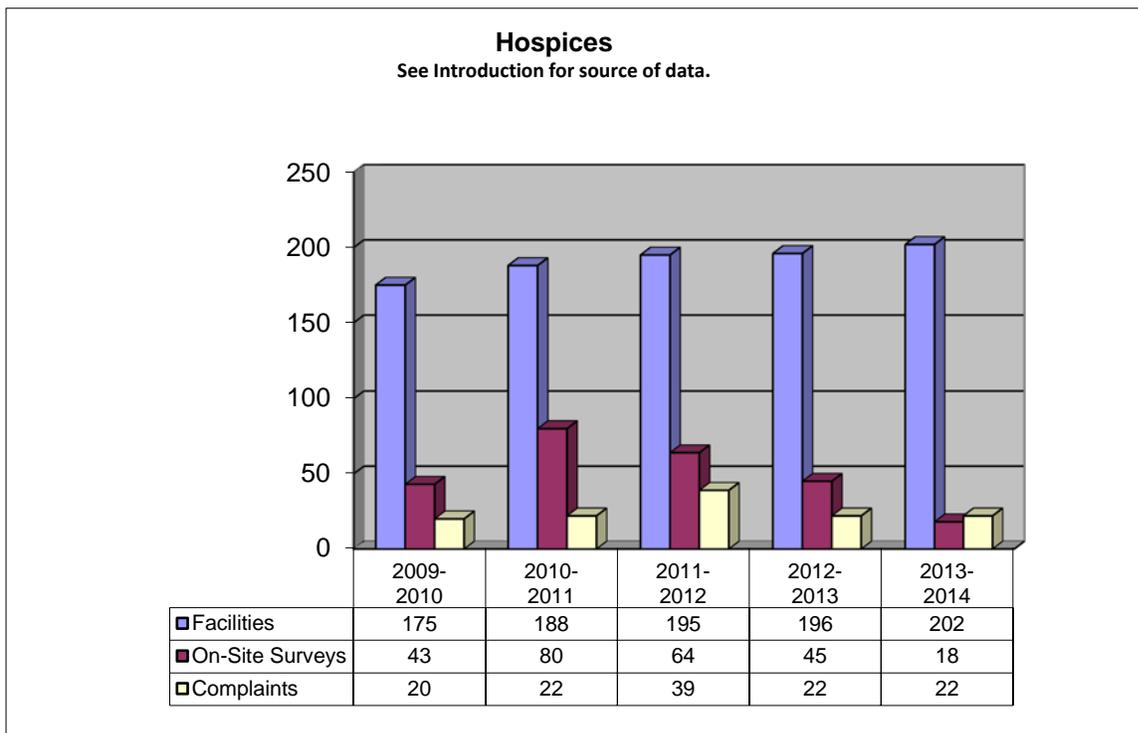
Hospices

The Department currently uses Medicare standards to license hospices. One hundred ninety-six hospices are licensed and Medicare-certified. Currently, no hospices are state licensed only.

Hospices are surveyed by on-site and off-site methods. 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 2013-14, the Department surveyed 18 facilities on-site, and 178 were licensed through off-site surveys.

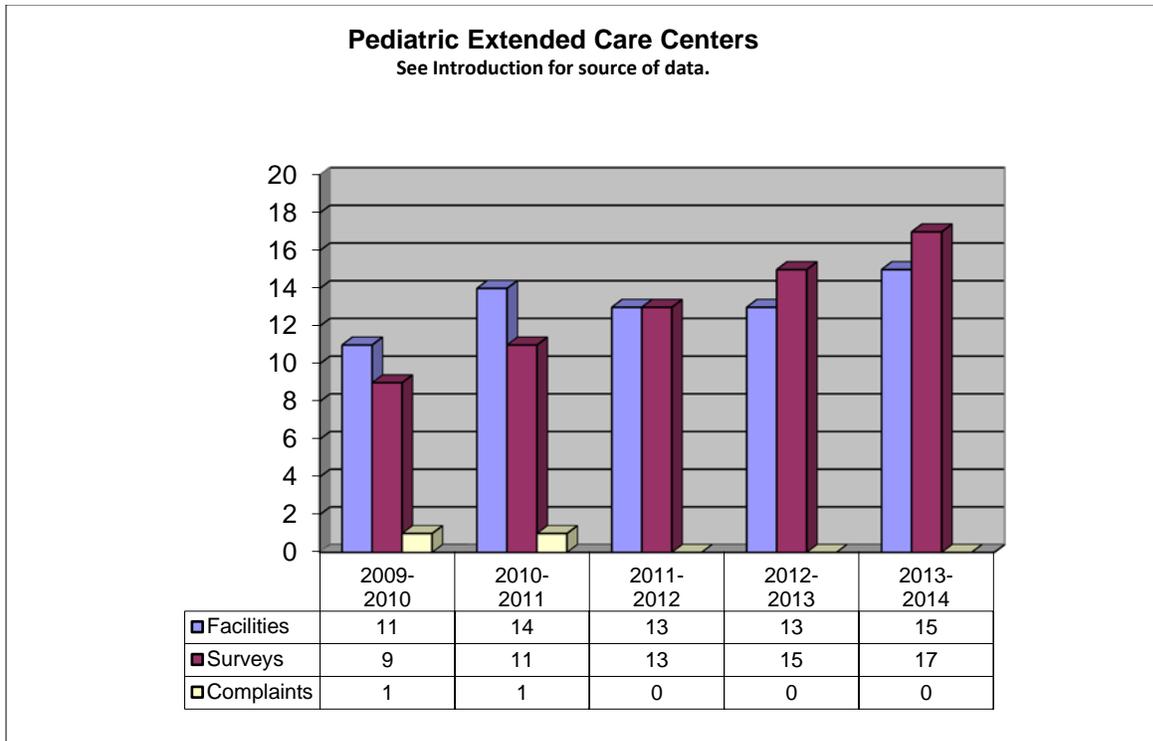
During SFY 2013-14, 22 hospice complaints were investigated. Of the 22 complaints investigated, 11 were substantiated. All providers with substantiated complaints submitted acceptable plans of correction, and no sanctions were imposed.

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 child care 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 2013-14 reporting period, there were 14 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, 2014, the Department licensed 156 acute care hospitals, 20 rehabilitation hospitals, six children's hospitals, 26 long-term acute care hospitals, and 13 critical access hospitals, for a total of 221 licensed acute care facilities.

The hospital licensure process begins with the scheduling of an announced on-site survey based on the licensure cycle. During SFY 2013-14, the Department issued 171 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 113 surveys during SFY 2013-14.

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 conducted to assess facility success in implementing and monitoring the plan of correction and compliance with licensure regulations. In SFY 2013-14, the Department completed 234 revisits, a decrease of 117 revisits over the prior SFY.

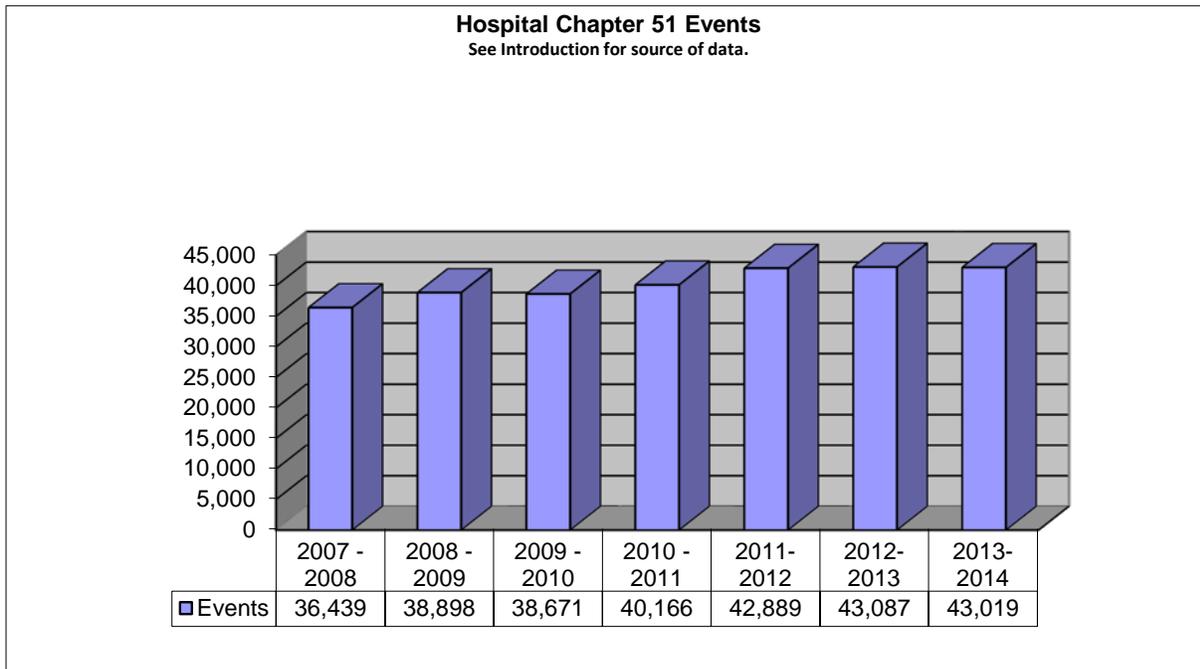
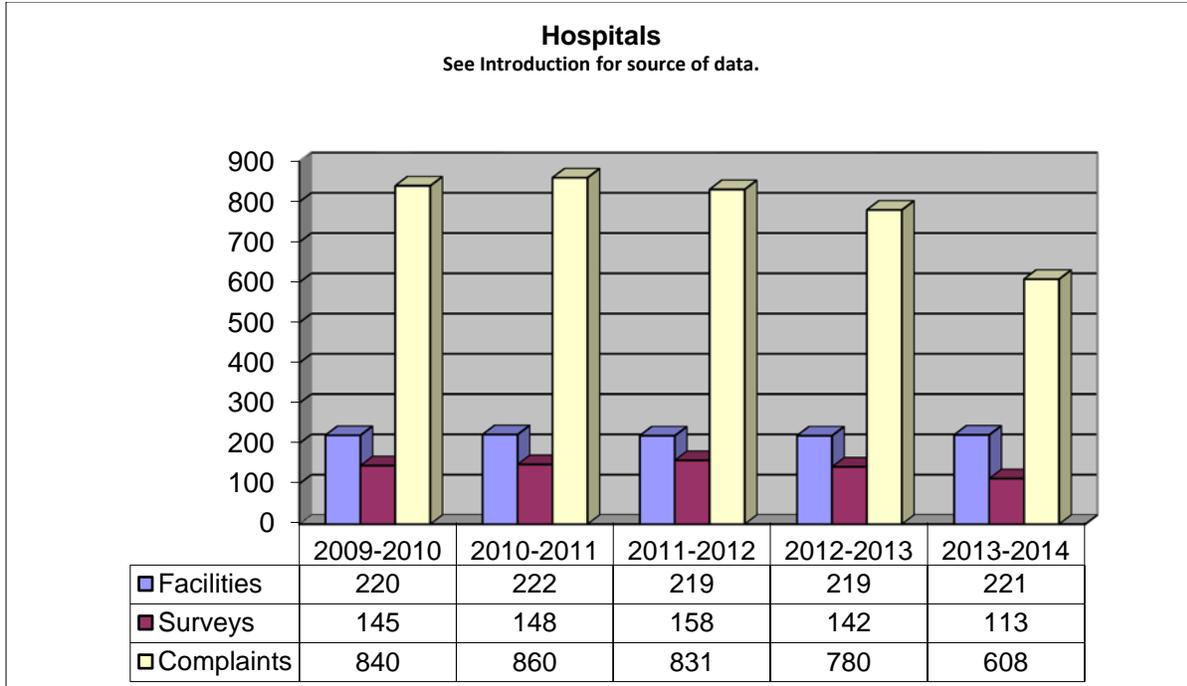
In accord with Act 60 of 2013, effective January 2014, the Department permits approved accreditation organization surveys to be used in lieu of state licensure surveys for hospitals only. Forty-two hospitals chose this option as of June 30, 2014. Surveys are conducted to the standards developed by the 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 758 program occupancy surveys in SFY 2013-14 for new services and/or new or renovated sites in hospitals, an increase of 76 surveys over the prior SFY.

The Department received a total of 608 complaints related to hospitals during this reporting period, a decrease of 172 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.



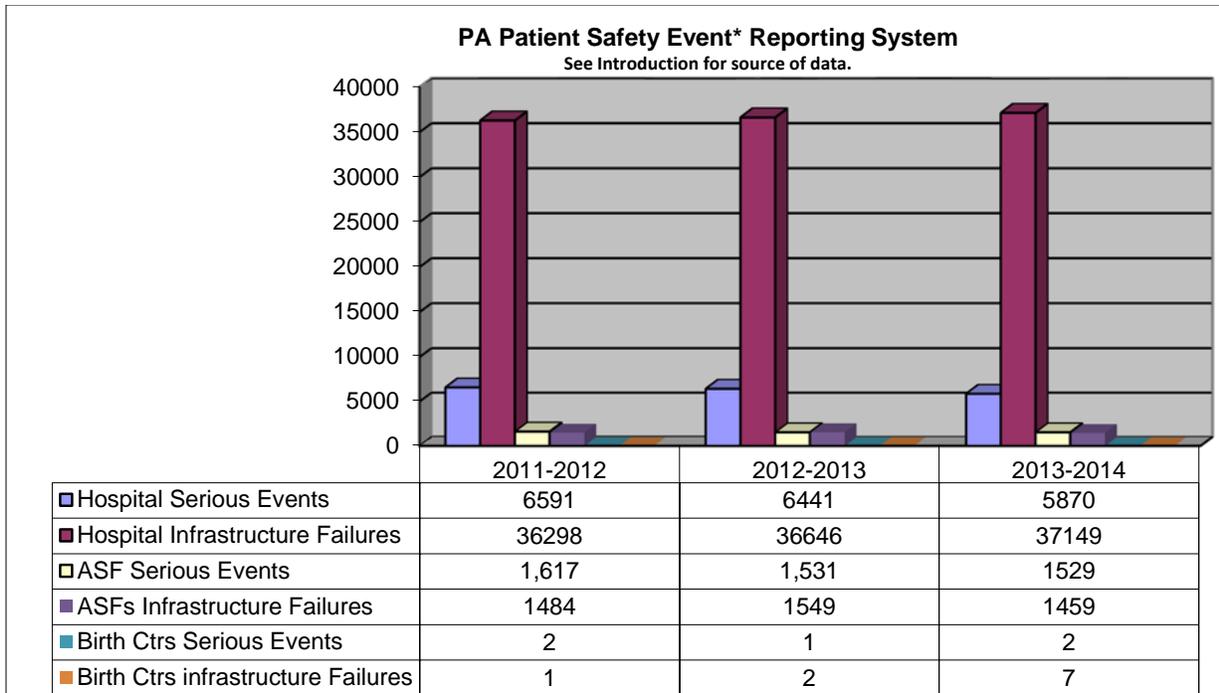
*Chapter 51 events are situations or occurrences at a facility that could seriously compromise quality assurance or patient safety.

Patient Safety Activities and Reporting

Act 13 of 2002 delegated specific responsibilities for the Department in implementing the Patient Safety Act (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 Patient Safety Authority (PSA). Hospitals (including private psychiatric hospitals), nursing care facilities, ambulatory surgical facilities, birth centers, and abortion providers performing 100 or more procedures per year are subject to the assessment. The surcharge receipts are placed in the PSA 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 2013-2014, the amount of \$6,490,752.95 was billed and collected.

The Department also receives, reviews, and responds to patient safety data reported by facilities in the PA Patient Safety Event Reporting System (PA PSERS). During FY 2013-14, 2988 serious events and infrastructure failures were reported by ASFs to the Department of Health, an increase of 66 from the prior year. Hospitals reported 43,019 serious events and infrastructure failures, an increase of 2,093 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 charts below.



***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, 2014, there were 705 nursing homes licensed in Pennsylvania, housing 88,334 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/Medicaid certification surveys, conducted for CMS, are also unannounced and are scheduled during a 15-month window dating from the previous Medicare/Medicaid certification survey. When possible, Medicare/Medicaid 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 resident care. The Department conducted 156 occupancy surveys of nursing care facilities during the fiscal year.

Category	Surveys Completed
Licensure/certifications	723
License only	8
Certification only	4
Initial certification	3
Complaints*	1,771

See Introduction for source of data.

All complaints are investigated. 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 2013-14, 88 percent of complaints were investigated on-site.

During SFY 2013-14, the Department conducted 1,089 follow-up visits to ensure the facilities corrected deficiencies and demonstrated compliance with all regulations. The most frequent deficient practices cited during SFY 2013-14 were: 1) maintaining residents at their highest practicable level; 2) documentation of clinical records; 3) infection control; 4) supervision and assistance to prevent accidents; and 5) sanitary food preparation, serving, and storage.

The Department conducts “monitoring visits” at facilities that have received 10 or more complaints. These unannounced visits are performed when a surveyor is in the vicinity of one of these 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 percent of surveys during evenings, weekends, and nights and also enhanced monitoring for poor-performing nursing homes. The monitoring includes on-site semi-annual certification, monitoring visits, and complaint investigations. Additional nursing home initiatives include: 1) monitoring of facilities that are experiencing fiscal difficulty (bankruptcy) and altering the survey protocols to include quality measures and enhanced investigative protocols for weight loss, dehydration, and pressure sores; 2) assessing a facility’s abuse prevention procedures; and 3) investigating residents who are receiving drugs considered dangerous to the geriatric population.

The Department investigates all complaints regarding the care of nursing care facility residents. Complaints are received from various sources including hotline calls, calls and written correspondence directed to the Central Office/Field Office, written correspondence to Central Office/Field Office, referrals from other agencies, Governor's Hotline, Attorney General's Office, legislators' offices, emails submitted to a designated complaint email address, or resident/family speaking directly to surveyors during an on-site visit. Additionally, complaints may be submitted on the Department of Health website. The Department's complaint system has provisions for appropriate referrals to other agencies for added coverage to the elderly in nursing homes. 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.

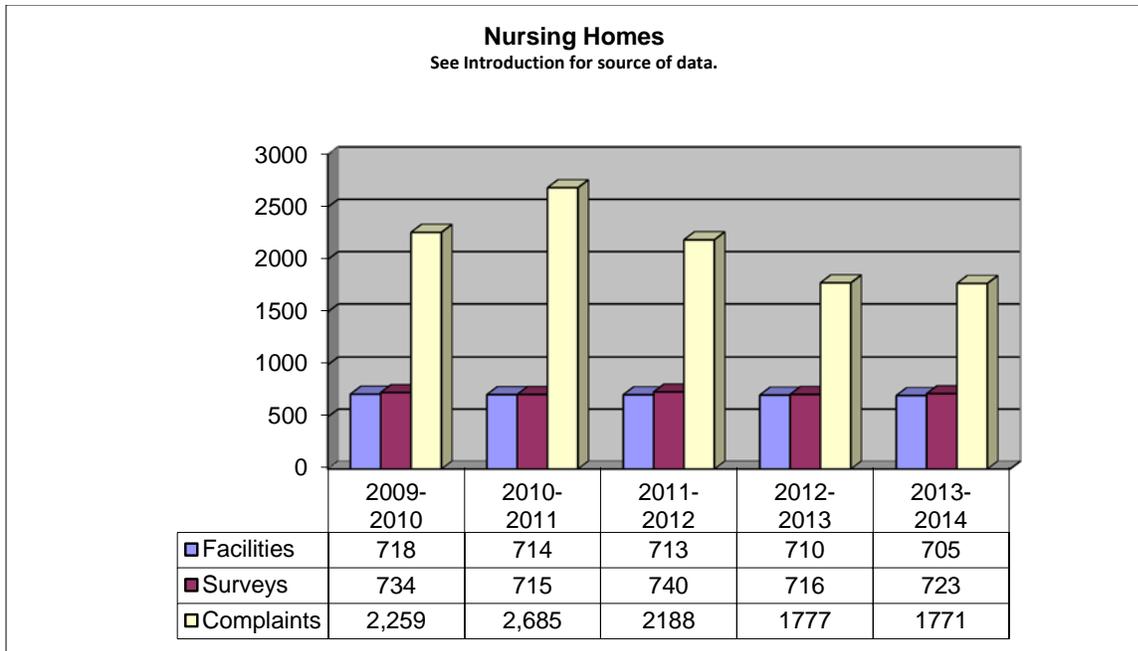
All complaint investigations are reviewed within two days of receipt so that the investigator is assured that residents are not in immediate jeopardy and that an acceptable resolution is being formulated, if necessary. If the nature of the complaint indicates residents could be seriously impacted by the circumstances, it is investigated immediately.

From July 1, 2013 through June 30, 2014, the Department received and investigated 1,771 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 resident 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 resident safety, to improve resident safety, and to focus future survey activity. During SFY 2013-14, 19,023 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 well being 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 280,623 nurse aides, 99,039 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 2013-14, the Department performed 1,379 Life Safety Code surveys and 838 Life Safety Code revisits for hospitals, ASFs, nursing care facilities, birth centers, intermediate care facilities, ESRDs (dialysis centers), hospices, and PECCs; eight new Medicare validation surveys and five Medicare validation revisit surveys were done.

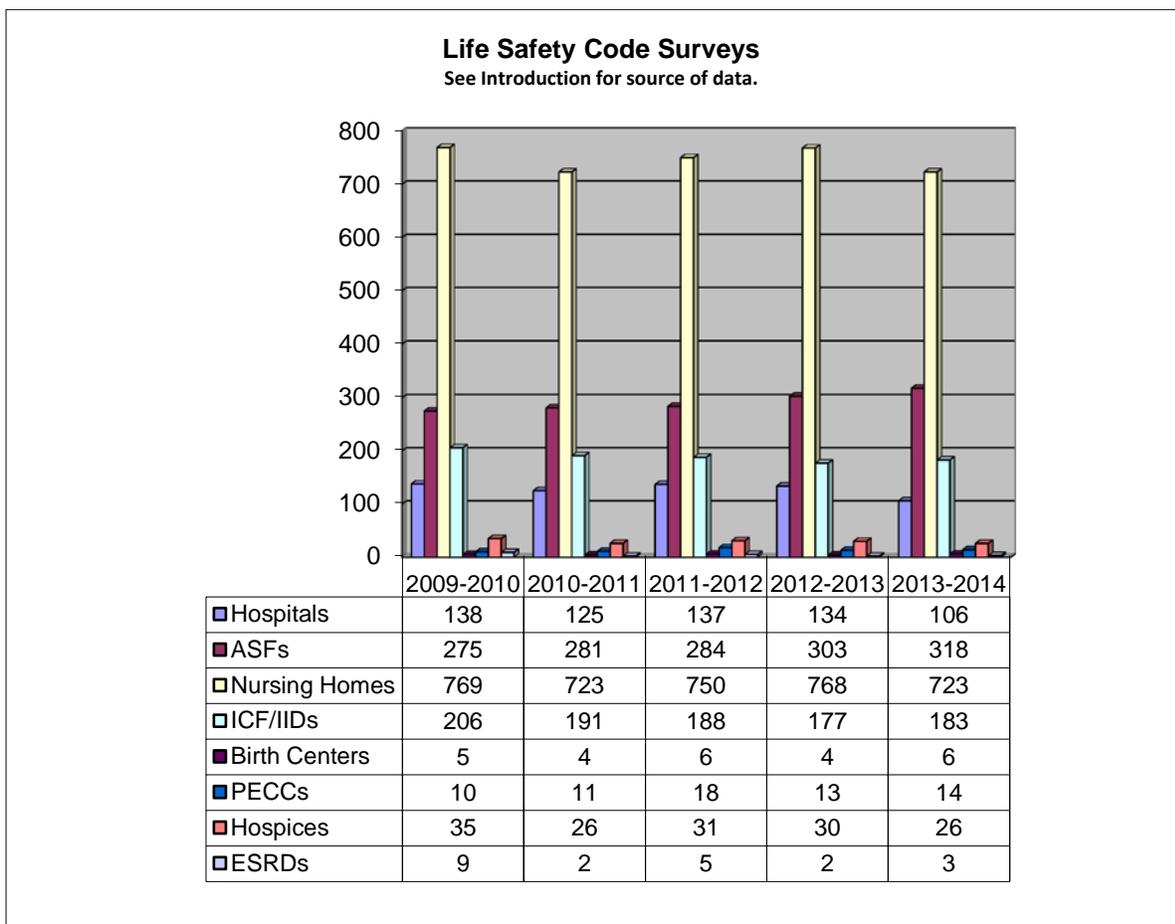
The Department also performed two new Fire Safety Evaluation System (FSES) surveys. All surveys to verify compliance, or substantial compliance in the case of nursing homes, are unannounced. An exception to this can be given for non-long-term care facilities, other than HHAs, which meet the criteria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

The Department also reviewed 2,779 plans for construction or renovation of health care facilities. Of these plans, 1,622 met safety standards and were approved.

These projects represent over \$2 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 2013-14, the Department's Division of Safety Inspection staff performed 1,025 occupancy inspections and 200 preoccupancy surveys.

The Department's safety inspection staff conducted 3,232 surveys during SFY 2013-14. The number of surveys by facility type for the past five years is displayed in the graph below.



ENFORCEMENT ACTIONS

The Department is authorized by The Health Care Facilities Act of 1979, P.L. 130, No. 48 (HCFA) and PA Code §51.41 and, in collaboration with CMS, to sanction health care facilities in serious violation of HCFA provisions 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 may sanction 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 DHS which licenses this unit)

Home health agencies: 8

Home care agencies: 3

Hospices: 0

Total Sanctions for nursing care facilities: 15

Provisional licenses = 3

Provisional licenses with a civil monetary penalty = 3

Civil monetary penalty only = 9

Temporary managers placed: 0

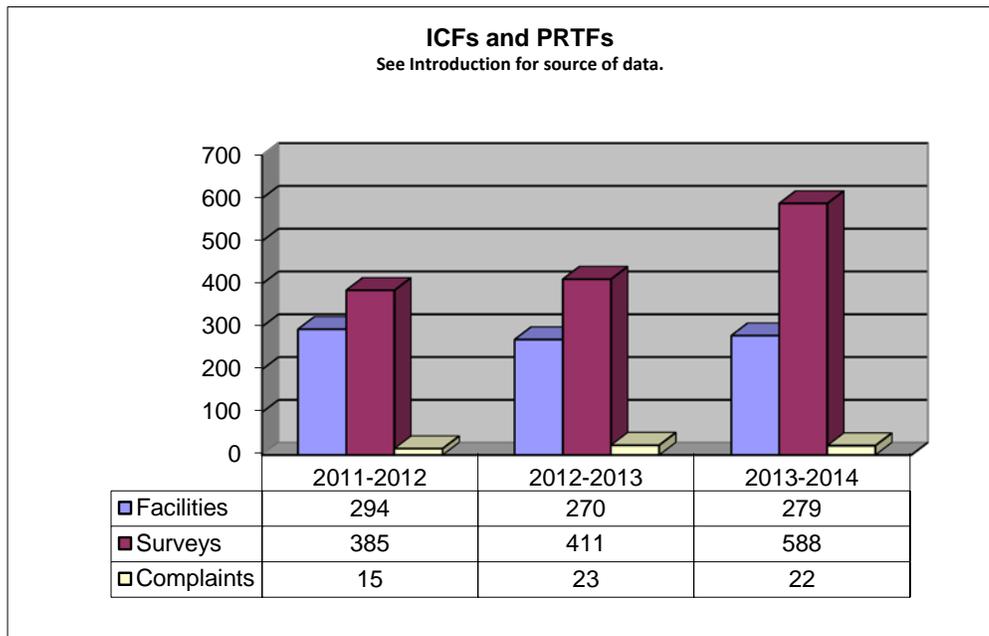
ADDITIONAL QUALITY ASSURANCE ACTIVITIES

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 181 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 98 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 that impact on resident health or safety are a high priority. The Department conducted 588 facility surveys and investigated 22 complaints during FY 2013-14.

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



Other Medicare Certified Programs

The Division of Home Health conducts Medicare recertification surveys every three years for 279 renal dialysis centers. In FY 2013-14, four centers were 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 2014 was 3,591,537, which is a 1.1 percent decrease when compared to the same quarter in 2013.

Managed care plans in Pennsylvania that provide services to public sector clients, such as CHIP and HealthChoices, show continued enrollment growth: Aetna Better Health (+23 percent), HealthAmerica of Pa. (+15.1 percent), Health Partners Plans (+9.5 percent) and UPMC For You (+23.8 percent).

In April 2014, UPMC Health Coverage received a certificate of authority to operate an HMO.

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 verifies 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 (CDC), 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 collaborations are used to educate hospital infection prevention staff on the requirements of Act 52 of 2007 and the National Healthcare Safety Network (NHSN) criteria that is periodically updated by the CDC. This is done to promote consistent reporting among hospitals.

Nursing homes began reporting infections into the Pennsylvania Patient Safety Reporting System (PA-PSRS) in June 2009. The Department reviews this data and provides individual facility data integrity and verification reports to allow a 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. Outreach telephone calls are also made to nursing homes to review the updated infection reporting criteria released in April 2014, as well as educate new staff on the requirements of Act 52 of 2007. This promotes consistent reporting among nursing homes.

National Precursor Log Exchange (NPLEx) – NEW in 2014

The Pennsylvania Department of Health is responsible for the implementation of Act 53 of 2013 (House Bill 602). This law requires that all Pa. pharmacies and retailers that sell over-the-counter cold and allergy medications containing ephedrine and/or pseudoephedrine (PSE) participate in a statewide, real-time, electronic PSE monitoring program for the purpose of tracking illegal PSE purchases. All pharmacies and retailers that dispense PSE were required to report, effective April 15, 2014.

In order to comply with Act 53, the Commonwealth of Pennsylvania has joined the National Precursor Log Exchange (NPLEx). Pharmacies and retailers in the commonwealth will be provided, at no charge to them, access to a Web-based database provided by Appriss where they can enter PSE sales data currently being gathered pursuant to the federal Combat Methamphetamine Act of 2005 (CMEA), rather than recording the information into a manual log or in-store computer system. The collected data will be viewable by law enforcement in keeping with CMEA and Act 53.

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 required of 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)	474
Manufacturer (non-prescription)	82
Distributor (prescription)	1083
Distributor (non-prescription)	415
Retailer (non-prescription)	7671
Devices	2718
Wholesaler/distributor licenses	737
Other (nonresident, List I, etc.)	681
Total	13861

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	No. of Registrants
Fitters	498
Dealers	472
Apprentices	81
Branches – dealer	550
Total	1607

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), which provide the perspective of hospitals and ambulatory surgery facilities. In January 2014, recommendations of the reporting standardization work group were published in the Pa. Bulletin with a 30-day comment period. In May 2014, the education and training work group convened to begin planning educational activities to ensure the shared understanding, interpretation, and application of these guidelines among staffs of the Department, PSA, and the involved facilities.

Influenza and Pneumococcal Disease Reporting

Act 95 of 2001, the Long-Term Care Resident and Employee Immunization Act, requires the Department to report every three years to the general assembly on the annual number of outbreaks in facilities due to influenza virus and pneumococcal disease, as well as the number of hospitalizations of facility residents each year due to influenza virus, pneumococcal disease, and complications thereof.

<u>Influenza</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Outbreaks due to influenza virus	161	435	534
Hospital admissions for flu symptoms	386	479	338
Hospital admissions for confirmed flu	88	206	204
Hospital admissions for flu complications	54	146	126
<u>Pneumococcal</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>
Outbreaks of pneumococcal disease	86	165	461
Hospital admissions for pneumococcal disease	2,081	2,085	1,913
Hospital admissions for pneumococcal disease complications	881	985	830

Stroke Centers

Act 54 of 2012, the Primary Stroke Center Recognition Act, established the Department's responsibility for recognizing acute care hospitals that have been certified as primary stroke centers by a nationally recognized accrediting body. Eighty-seven hospitals were approved. A list of these hospitals is available on the Department's website.