

Report of the Quality Assurance Programs

Office of Quality Assurance

Report for Fiscal Year
2018-2019



pennsylvania
DEPARTMENT OF HEALTH

Contents

Introduction	3
Survey and Certification Program	3
Ambulatory Surgical Facilities	4
Birth Centers	5
Home Health Agencies	6
Home Care Agencies	8
Hospices	9
Pediatric Extended Care Centers	10
Hospitals	11
Patient Safety Activities and Reporting	13
Nursing Care Facilities	14
CMS MDS/Staffing-focused Surveys	17
Nurse Aide Registry	17
Safety Inspection	18
Enforcement Actions	19
Additional Quality Assurance Activities	20
Community Mental Health Centers (CMHC)	21
Other Medicare Certified Programs	21
Indoor Tanning Facilities	21
Healthcare Associated Infection Prevention (HAIP)	22
National Precursor Log Exchange (NPLEx)	22
Drug, Device and Cosmetic (DDC) Program	23
Hearing Aid Program	23
	24
Bureau of Community Program Licensure and Certification	24
Bureau of Facility Licensure and Certification (BFLC)	24
References	25

Introduction

The Department of Health (Department) administers the Health Care Facilities Act of 1979 (Act) [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 and Certification and Community Program Licensure and Certification. The Act defines health care facilities as: ambulatory surgical facilities, hospitals, long-term care nursing facilities, birth centers and home health care agencies. 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 became subject to ambulatory surgical facility regulations and standards.

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 on additional quality assurance functions performed by the Department. The health care facility pages on the Department's website contain information regarding health care facility compliance with regulatory requirements for licensure and for certification.

The Department functions as both the state licensing agency and the state survey agency certifying facilities for the Centers for Medicare and Medicaid Services (CMS). The difference between the two roles is nuanced. Licensure permits a facility to operate in Pennsylvania. Certification permits a facility to claim and receive payment for services rendered under the Medicare and Medicaid programs. When the Department conducts a survey of a facility that is both licensed and certified, it essentially acts as a regulator for the state and as an agent for CMS. Facilities are liable to be sanctioned by both.

The Department conducts both routine and special inspections of health care facilities to determine ongoing compliance with regulatory requirements that 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 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 is for purposes of licensure and certification. It is not an admission of wrongdoing or liability on the part of the facility and should not be regarded as such.

Survey and Certification Program

In addition to surveying facilities to ensure that state licensure standards are met, the Department also surveys and certifies facilities for the federal Medicare and Medicaid programs. Certification allows facilities to be eligible to receive reimbursement for services rendered to Medicare and Medicaid recipients. When regulatory deficiencies are identified, the Department and CMS work together to ensure that appropriate corrections are made promptly and implemented effectively.

The Department maintains a staff of approximately 200 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 may be augmented with surveyors who are psychologists, nutritionists, social workers, and occupational or speech therapists.

The Department and 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, federal 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 upon the nature of the complaint.

The following pages provide descriptive information on each facility type and state fiscal year (SFY) 2018-2019 survey and complaint data. In addition, information is provided about sanctions as defined in 28 PA Code §51.41 and patient safety data reported by ambulatory surgical facilities, hospitals and birth centers.

Ambulatory Surgical Facilities

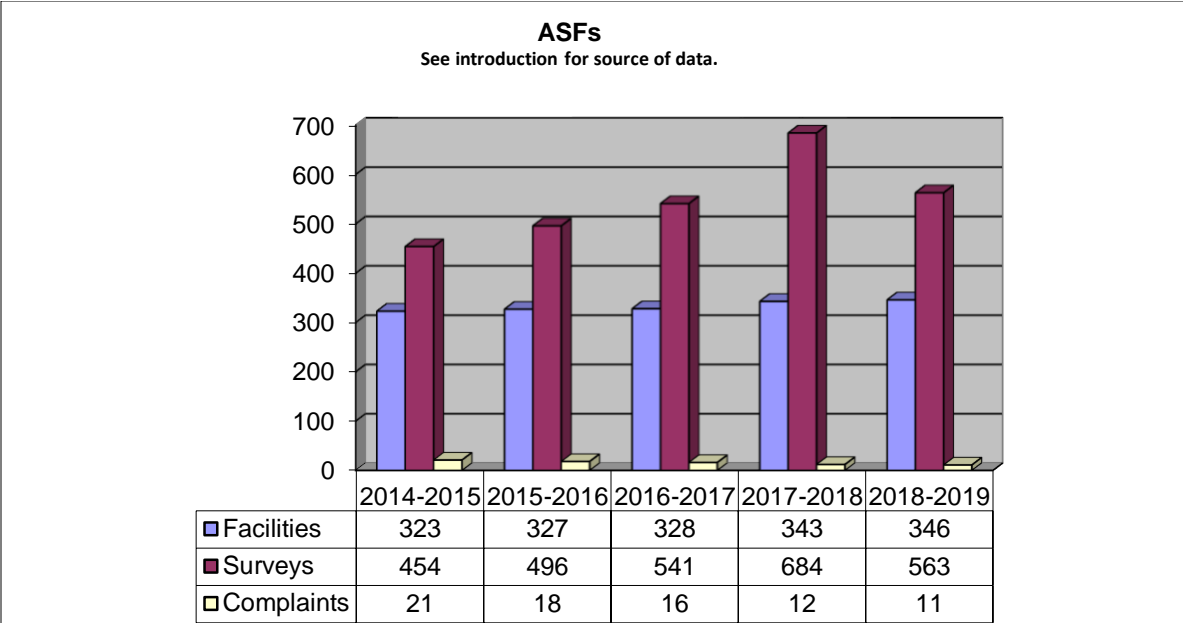
As of June 30, 2019, there were 346 ambulatory surgical facilities (ASFs) licensed and/or registered in Pennsylvania, an increase of fifteen ASFs over the previous SFY. Abortion facilities (ABF) are included in these counts. ASFs are classified as A, B or C based on procedures performed, patient status 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 11 complaints related to ASFs during the report period. Of the 11 complaints received, were investigated during the 2017/18 fiscal year. The remaining complaints will be investigated in 2018/19. In addition, 336 licensure/certification surveys, 49 occupancy surveys and 145 revisits were conducted for ASFs in SFY 2018-19, representing an increase of 18 licensure/certification surveys, 14 occupancy surveys and 116 revisits over prior SFY.

The number of ASFs, surveys and complaints over the last five years are displayed in Figure 1. Additional information about serious events and infrastructure failures reported by ASFs is provided in Figure 9.

Figure 1. Number of ASFs, Surveys Conducted and Complaints Received



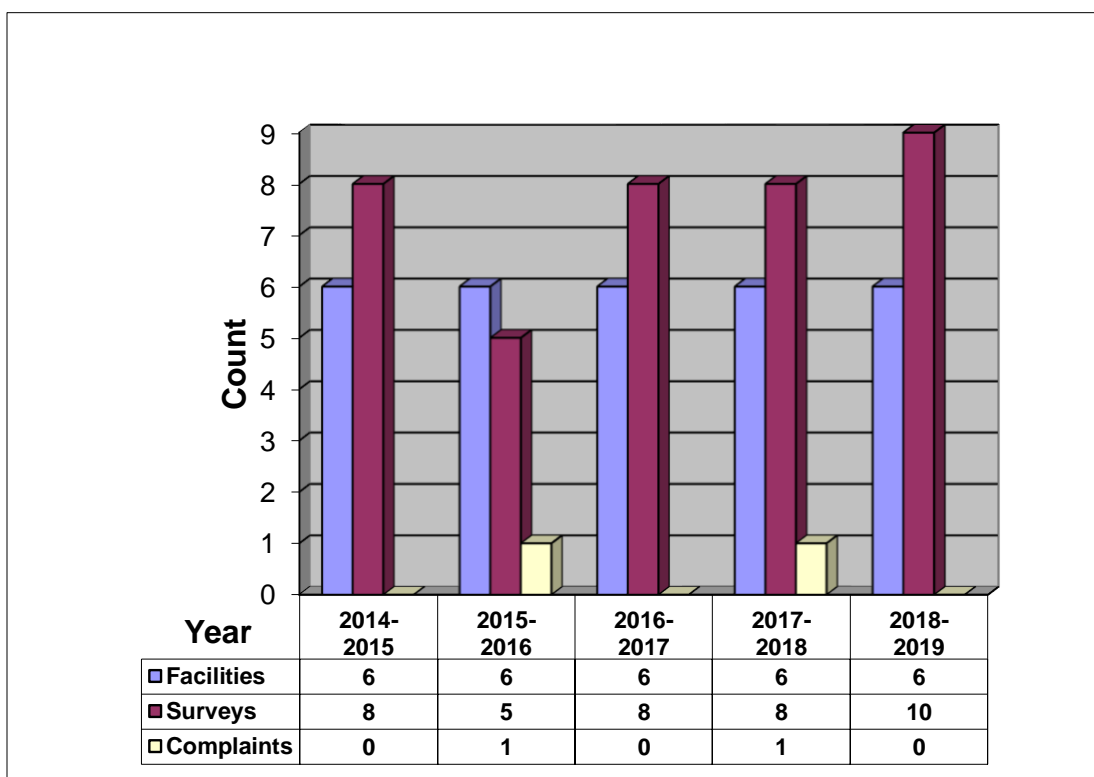
Source: Quality Assurance Survey Agency Information System (SAIS), 2019
Surveys count includes certification and licensure surveys, validation surveys, complaint surveys, revisit surveys, occupancy surveys and special monitoring surveys.

Birth Centers

There are six licensed birth centers in the commonwealth. Birth centers provide care before, during and after delivery to mothers-to-be who are low-risk. Unannounced birth center licensure surveys are conducted on-site annually. The Department did not receive any complaints regarding the care and services provided by birth centers during this reporting.

The number of birth centers, all surveys conducted and complaints over the last five years are displayed in Figure 2. Additional information about serious events and infrastructure failures reported by birth centers is provided in Figure 9.

Figure 2. Number of Birth Centers Surveys Conducted and Complaints Received



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Home Health Agencies

Home health agencies (HHA), not to be confused with Home Care Agencies or Home Care Registries, must be licensed by the commonwealth and must provide part-time intermittent skilled nursing services plus at least one other therapeutic service (physical therapy, occupational therapy, speech therapy, medical social services or home health aides) to individuals in their homes or other independent living environments. Licensure requires a survey that indicates an applicant is in substantial compliance with HHA regulations. HHAs choosing to participate in the Medicare program must also be certified as eligible. The Department conducts certification activities (which include surveys and complaint investigations) for the federal government. Qualified nurse surveyors conduct state licensure surveys, federal certification surveys and complaint investigations.

During this reporting period, there were 588 HHAs operating in the commonwealth, an increase of eight agencies from the previous reporting period. All 588 are licensed. The Department recommended certification for 440 HHAs, which enables them to receive Medicare reimbursement from CMS. The remaining 148 HHAs are state-licensed only, because they choose not to participate in the federal reimbursement programs. The Department conducted 212 Medicare and/or state licensure on-site surveys in SFY 2018-19, and 18 agencies were issued state provisional licenses and civil monetary penalties. Medicare-certified HHAs must comply with federal regulations, which require an onsite 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 onsite surveys are unannounced. The Department also conducts onsite surveys on an additional 5 percent targeted sample of agencies that are selected based on agency

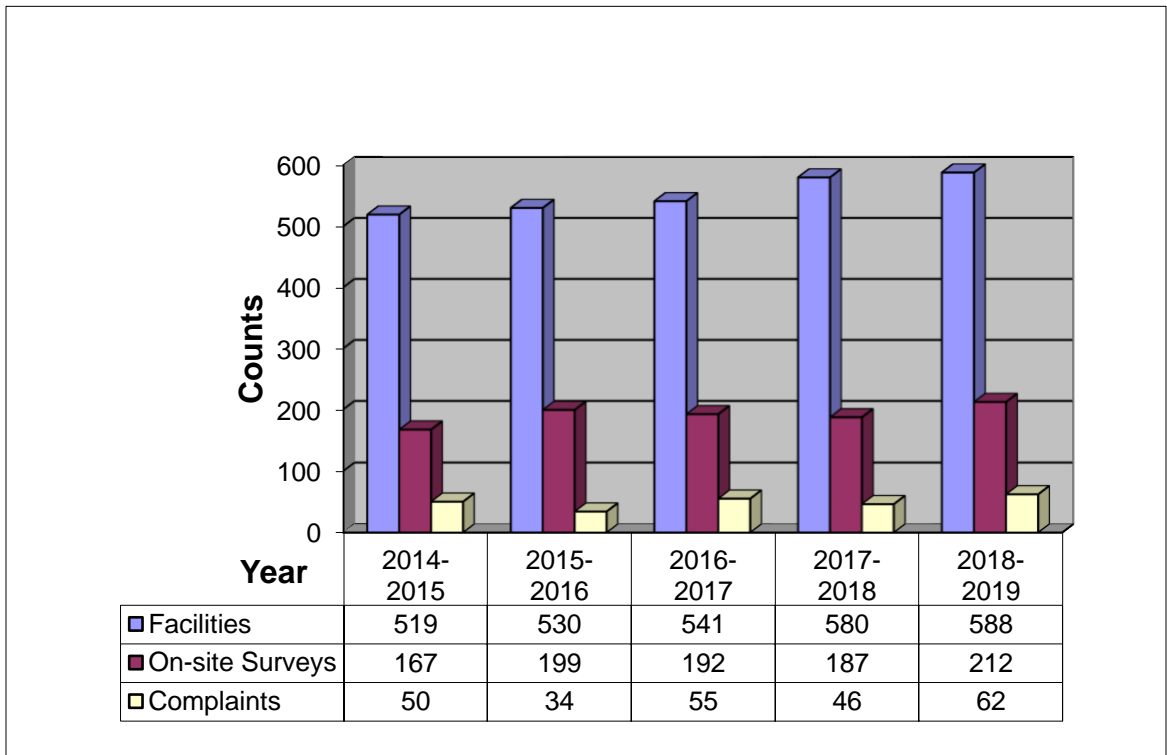
performance data. Additionally, validation surveys are conducted on 5 percent of deemed agencies. A HHA that has been granted “deemed status” is one that has been accredited by a CMS-approved accrediting body and is complying with the applicable federal regulatory standards. Deemed agencies are exempt from Medicare recertification surveys from the state agency and are under the jurisdiction of the CMS-approved accreditation program for continued compliance oversight.

In order to coordinate the federal 36-month survey time frame with the state requirement for annual licensure surveys, offsite surveys are conducted for state licensure purposes. An offsite 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.

During SFY 2018-19, the HHAs survey schedule was 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.

The Department received and investigated 62 HHA complaints, an increase of 16 complaint investigations from the previous reporting period. Of the 62 complaints investigated, 23 were substantiated and provisional licenses and civil monetary penalties were imposed. In addition to complaints, the Department tracks events that are reported by HHAs through a mandatory web-based electronic event report system (ERS) in accordance with 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, Licensure and Certification surveys and complaints over the last five years are displayed in Figure 3.

Figure 3. Number of Home Health Agencies Surveys Conducted and Complaints Received



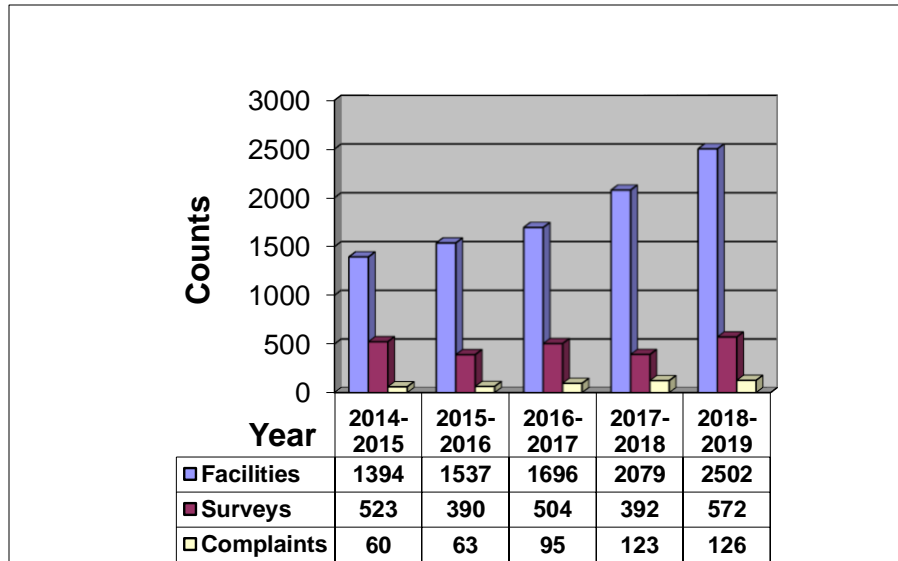
Source: Quality Assurance Survey Agency Information System (SAIS),2019

Home Care Agencies

Home care agencies and home care registries provide non-skilled services (including personal care, respite care, specialized cared, companionship services, and assistance with instrumental activities of daily living) to individuals in their homes or other independent living environments. A home care agency supplies, arranges, or schedules employees to provide home care services while a home care registry supplies, arranges, or refers independent contractors to provide home care services.

State licensure regulations for home care agencies and registries became effective in December 2009. Newly licensed home care agencies are surveyed within five months after initial licensure. Those agencies serving three or more clients are surveyed. Over the last year, the number of agencies and registries increased by 423 from 2,079 to 2,502. The four-year growth rate for home care agencies and registries is approximately 19 percent. The number of agencies, surveys conducted, and complaints are displayed in Figure 4. Thirteen agencies were issued a provisional license and monetary penalty.

Figure 4. Number of Home Care Agencies and Registries Surveys Conducted and Complaints Received



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Note: Survey count only includes certification and licensure surveys.

Hospices

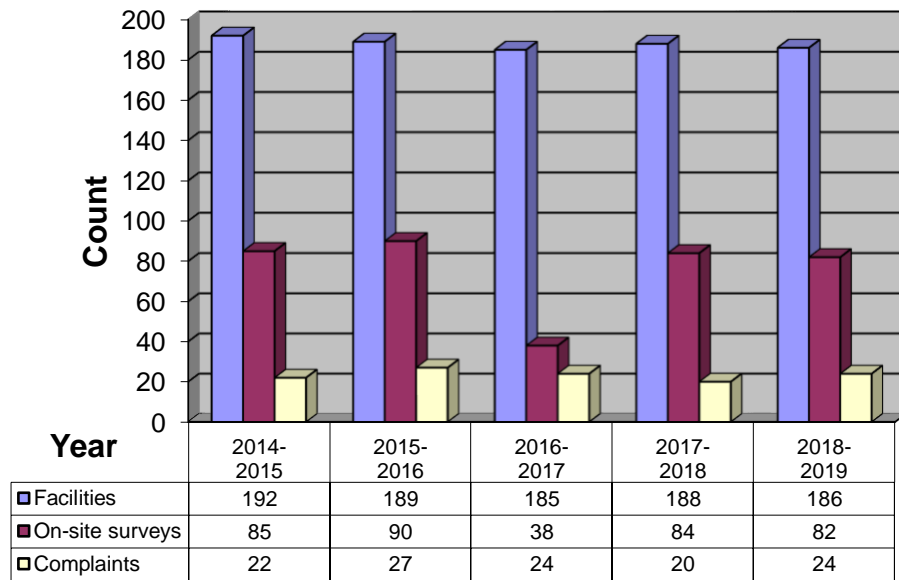
The Department currently uses Medicare standards to license hospices. There are currently 186 hospices that are licensed and Medicare-certified. There are currently no facilities that are state licensed only.

Hospices are surveyed by onsite and offsite methods. An offsite 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 2018-19, the Department surveyed 82 facilities onsite, and 104 were licensed through offsite surveys. Four providers received provisional licenses and civil monetary penalties.

During SFY 2018-19, 24 hospice complaints were investigated. Of the 24 complaints investigated, nine were substantiated. All providers with substantiated complaints submitted acceptable plans of correction, but two providers received a provisional license and civil monetary penalty.

The number of hospices, onsite surveys conducted, and complaints received for the past five years are displayed in Figure 5. The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 mandated surveys of Medicare certified hospices no less frequently than every 36 months; previously, these facilities were surveyed every six years. The division will be in compliance with the act. By April 2019, all certified facilities will have been surveyed in the prior 36 months accounting to CMS regulation changes.

Figure 5. Number of Hospices On-Site Surveys Conducted and Complaints Received



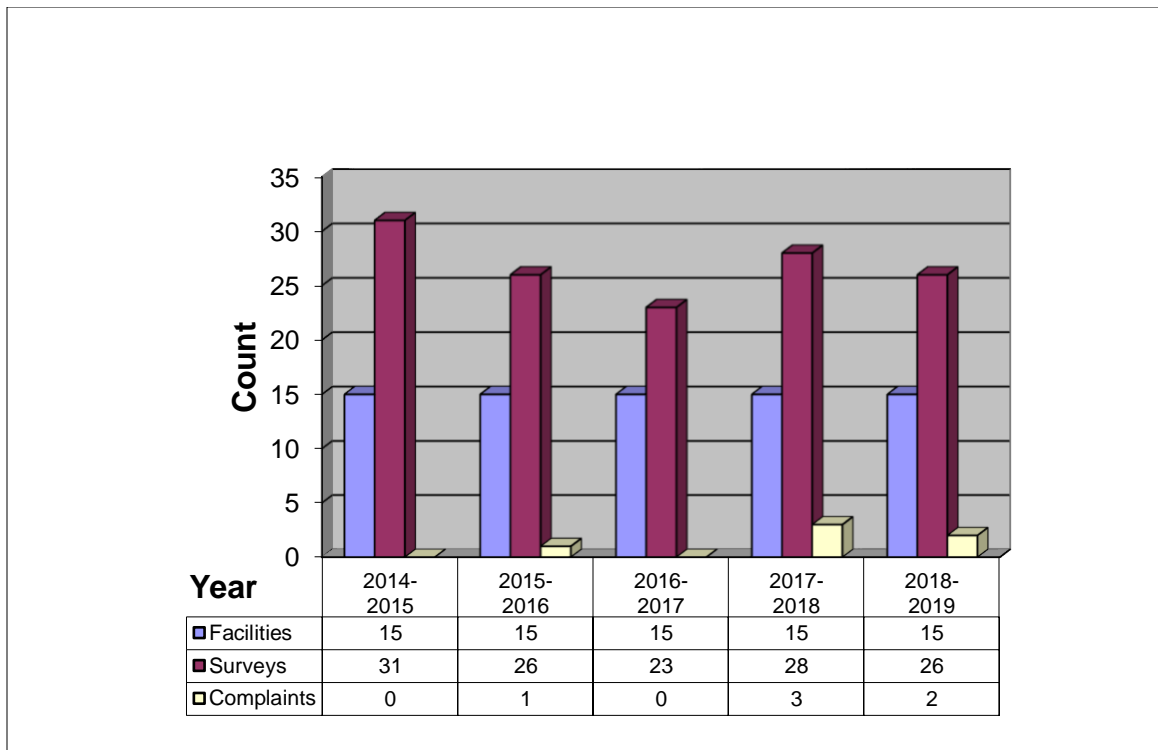
Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Note: Survey count only includes licensure and certification surveys.

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 are required to have a minimum of one supervisor employed for every six children, and a minimum of one direct caregiving staff available for every three children at all times. PECCs do not provide 24-hour care, and the children do not stay overnight in the facility. 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. PECCs are licensed annually using an unannounced onsite survey. During the SFY 2018-19 reporting period, there were 15 PECC facilities licensed in the commonwealth. Two provisional licenses and two civil monetary penalties were imposed. The Department received two complaints regarding the care and services provided by these PECCs, neither of which were substantiated. Figure 6 demonstrates the number of pediatric extended care centers, the number of surveys conducted and complaints received over the past five years.

Figure 6. Number of Pediatric Extended Care Centers, Surveys Conducted* and Complaints Received



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Note: Surveys conducted include 14 re-licensure surveys, 2 complaint surveys, 1 occupancy survey and 9 revisits.

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, as they are licensed by the federal government. Psychiatric hospitals are licensed by the Pennsylvania Department of Human Services

As of June 30, 2018, the Department licensed 149 acute care hospitals, 21 rehabilitation hospitals, six children’s hospitals, 20 long-term acute care hospitals and 15 critical access hospitals, for a total of 211 licensed acute care facilities.

The hospital licensure process begins with the scheduling of an announced onsite survey based on the licensure cycle. During SFY 2018-19, the Department issued 142 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 35 licensure surveys during SFY 2018-19.

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 2018-19, the Department completed 198 revisits, a decrease of 61 revisits over the prior SFY. Effective January 2014 and in accordance with Act 60 of 2013, the Department permits approved accreditation organization surveys to be used in lieu of state licensure surveys for hospitals. Eighty-six hospitals chose this option for the 2018-19 period. Surveys are

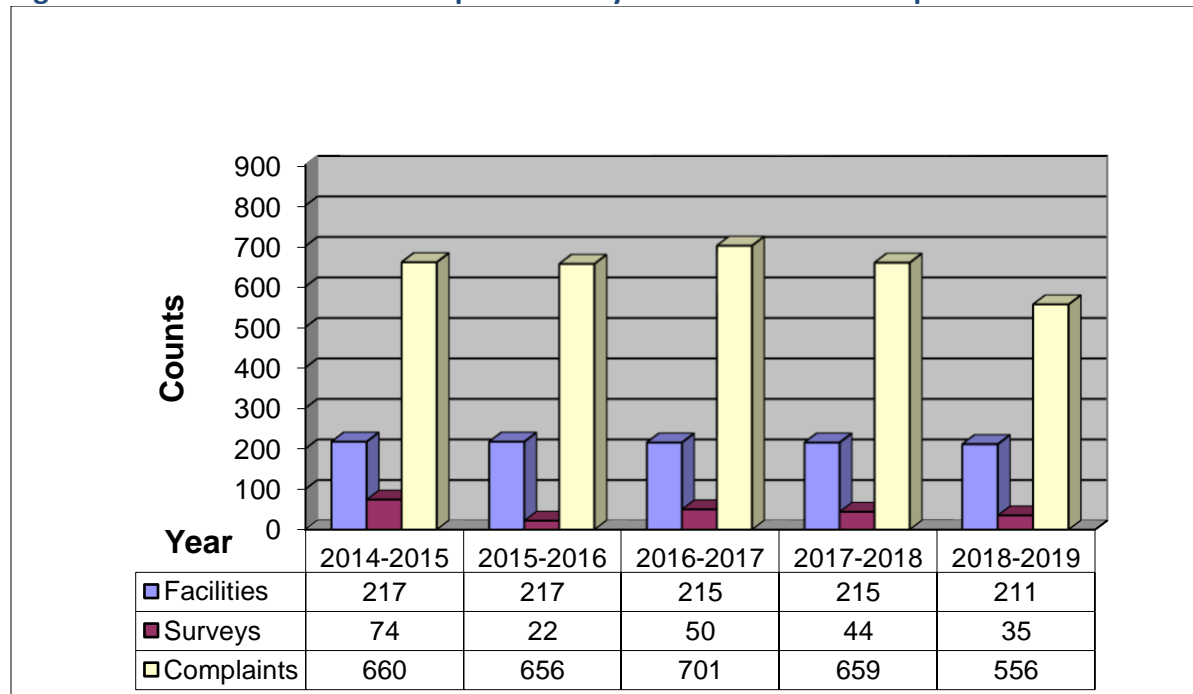
conducted to the standards developed by the accreditation organization unless state law standards are stricter, in which case the state law standards are applicable.

Any hospital that plans to offer services to the public 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 955 program occupancy surveys in SFY 2018-19 for new services and/or new or renovated sites in hospitals, an increase of 84 surveys over the prior SFY.

The Department received a total of 556 complaints related to hospitals during this reporting period, a decrease of 103 complaints over the prior SFY. All complaints are thoroughly investigated. If an onsite 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. Charter 51 events of the Health Care Facilities Regulations for the past five years are displayed in Figure 8.

The numbers of licensed hospitals, surveys and complaints are displayed in Figure 7.

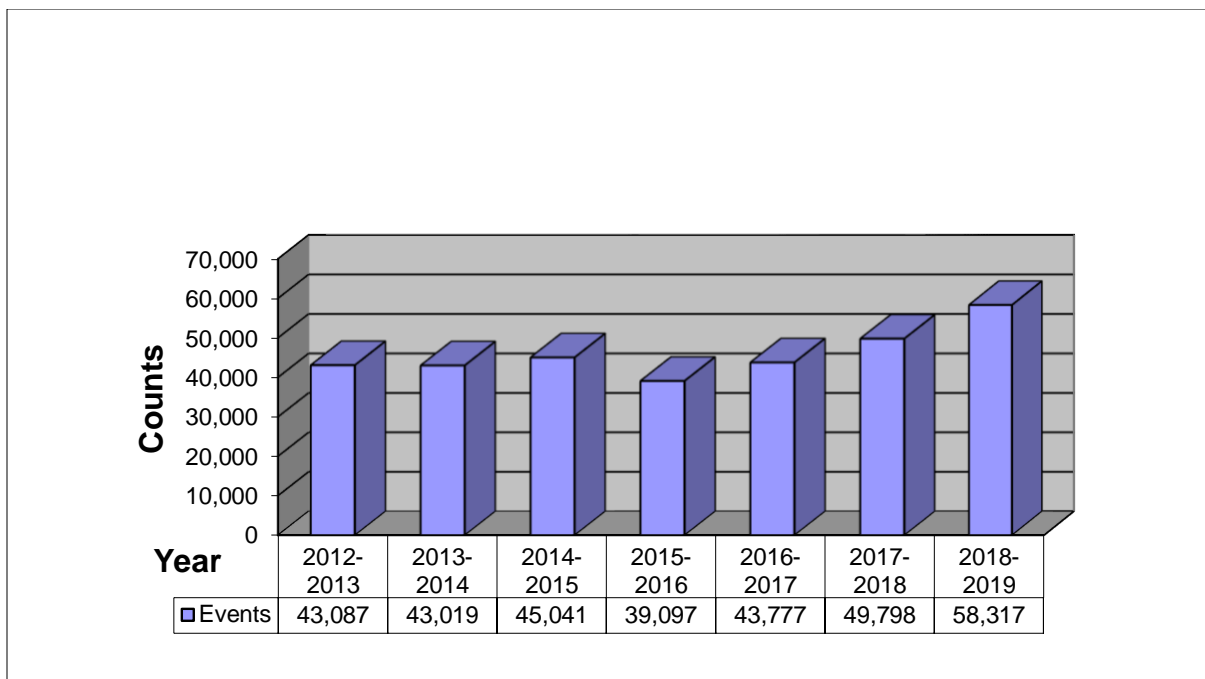
Figure 7. Number of Licensed Hospitals Surveys Conducted and Complaints Received



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Note: In 2018-19, 86 hospitals chose their approved accreditation organization surveys to be used in lieu of state licensure surveys.

Figure 8. Chapter 51- Events in Health Care Facilities



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

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

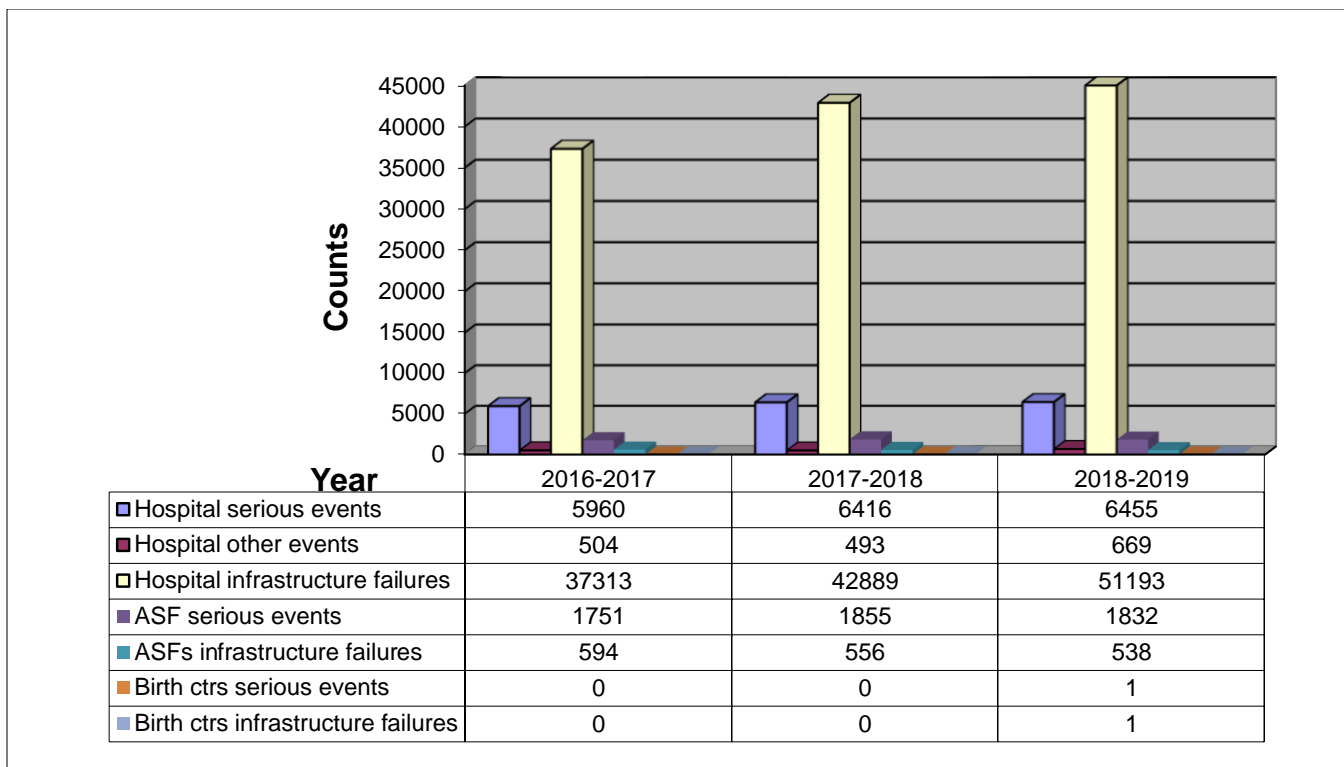
Patient Safety Activities and Reporting

Act 13 of 2002 delegated specific responsibilities for the Department in implementing the Patient Safety Act (PSA). 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 relicensure surveys, as well as during complaint and/or event investigations.

As required by the act, the Department collects the annual surcharge based on a per unit (bed, procedure or operating room) assessment set by the PSA. Hospitals (including private psychiatric hospitals), nursing care facilities, ambulatory surgical facilities, birth centers, and abortion providers that perform 100 or more procedures per year are subject to this 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 2018-19, \$7,974,257.03 was 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 SFY 2018-19, 2,370 serious events and infrastructure failures were reported by ASFs to the Department of Health, a decrease of 41 from the prior year. Hospitals reported 58,317 serious events and infrastructure failures, an increase of 8,519 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 displayed in Figure 9.

Figure 9. Serious Events and Infrastructure Failures by Facility Type



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Note: 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, 2019, there were 699 nursing care facilities licensed in Pennsylvania, housing 88,108 long-term care beds. These facilities are surveyed for yearly licensure on a variable schedule. All onsite surveys for licensure, revisits, complaint investigations, and reports of incidents 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 care facility 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 80 occupancy surveys of nursing care facilities during the fiscal year.

Table 1. Nursing Care Facility Surveys Completed in the 2018-2019 Fiscal Year

Survey Category	Completed FY 18-19
Licensure and/or certification	733
Complaints*	2,368

Total licensure, certification and complaint surveys

3,101

Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Note: This number depicts the number of surveys completed due to complaints received. There were 3,712 complaints received in fiscal year 2018-19, although multiple complaints could be investigated in a single survey.

During SFY 2018-19, the Department conducted 1,525 follow-up visits to ensure that the facilities corrected deficiencies and demonstrated compliance with all regulations. The most frequent deficient practices cited June 30, 2017, through Nov. 27, 2017, were: 1) maintaining residents' health at the highest practicable level; 2) supervision and assistance to prevent accidents; 3) infection control; 4) sanitary food preparation, serving and storage; 5) documentation of clinical records; and 6) development of care plans. The most frequent deficient practices using revised federal regulations that became effective on Nov. 28, 2018, were: 1) maintaining residents' health at the highest practicable level; 2) infection control; 3) supervision and assistance to prevent accidents; 4) sanitary food preparation, serving and storage; 5) development of care plans; and 6) documentation of clinical records.

The Department conducts "monitoring visits" at facilities that demonstrate performance problems. These unannounced visits are performed when a surveyor, because of other survey assignments, is in the vicinity of one of these designated nursing homes. This efficiency technique enables more frequent spot-checks to monitor the progress of high-risk facilities.

The federal government provides states with grant awards to assist with the cost of nursing care facility survey initiatives. To receive the funding, the Department must conduct 10 percent of surveys during evenings, weekends and nights and conduct enhanced monitoring of poor-performing nursing care facilities. The grants provide funding for onsite semi-annual certification, monitoring visits and complaint investigations. Additional survey process initiatives that are supported by the federal funding 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. When multiple complaints are received simultaneously, they may be investigated during the same survey for added efficiency. The majority of complaints are investigated through onsite visits. However, offsite complaint investigations may also be conducted 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 2018-19, 99 percent of complaints were investigated onsite.

Complaints are received from various sources including hotline calls, written correspondence, calls directed to the central office and field offices, referrals from other agencies, the Governor's Hotline, the Attorney General's Office, legislators' offices, emails submitted to a designated complaint email address, as well as residents and their families speaking directly to surveyors during an onsite visit. Additionally, complaints may be submitted via the Department of Health website. The Department's complaint system has provisions for appropriate referrals to other agencies responsible for the welfare of the elderly in nursing care facilities. Some issues are identified in the complaint process that

are not under the jurisdiction of the division. In those cases, referrals are made to other Department offices, state agencies or local authorities as appropriate.

All received complaints are triaged according to federal regulations to determine appropriate priority. If the nature of the complaint indicates that residents could be seriously impacted by the circumstances alleged in the complaint, it is prioritized as an immediate jeopardy (IJ) priority, and an investigation is started onsite within two business days. Complaints that are not IJ priority are prioritized using the options below. Deadlines for those priorities restrict the days from complaint receipt to onsite investigation initiation. Offsite investigation deadlines establish the number of days from complaint receipt to investigation completion:

Non IJ High – 10 business days

Non IJ Medium – 45 calendar days

Non IJ Low – 120 calendar days

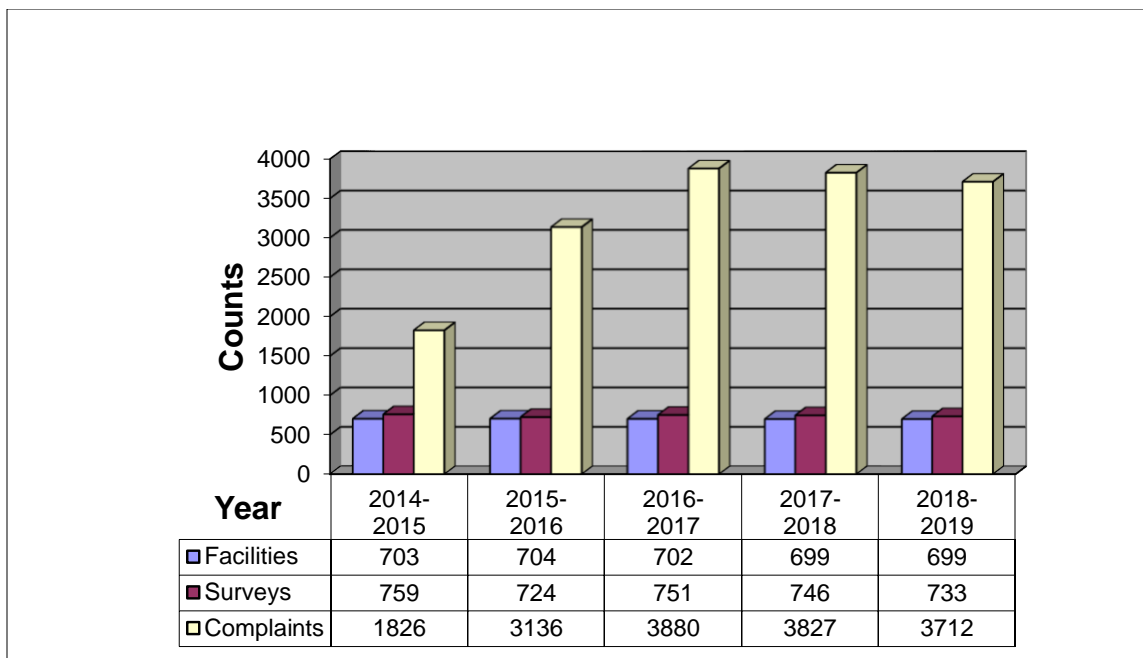
Offsite investigation – 30 calendar days

During SFY 2018-19, the Department received 3,712 complaints, which resulted in 2,368 surveys.

In accordance with 28 Pa. Code Chapter 51, the Department tracks events that are reported by nursing care facilities 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 onsite investigation or integration into other survey activities. Patterns found in the assessment of the event reports alert staff to issues affecting resident safety, thereby helping to improve resident safety and to focus future survey activity. During SFY 2018-19, 29,351 events were reported.

The number of facilities, surveys and complaints for the past five years are displayed in Figure 11.

Figure 11. Number of Nursing Care Facilities, Licensure and/or Certification Surveys Conducted and Complaints Received



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

CMS MDS/Staffing-Focused Surveys

CMS has revised the Medicare and Medicaid Conditions of Participation for Nursing Care Facilities. The revised conditions are being implemented through a three-phase process. Phase two of this implementation was effective 11/28/17 and involved a renumbering of federal citations and a revision to the survey process. Preparation for the revised survey process included 1) in-person trainings for all Division of Nursing Care Facilities (DNCF) staff in October and November 2017; 2) substantial equipment purchases; and 3) the completion of seven mock (practice) surveys across the state in November 2017.

Prior to the implementation of the revised federal survey process in 2017, the DNCF conducted separate surveys to evaluate facilities' compliance with requirements for completing the resident assessment tool called the Minimum Data Set (MDS). The MDS is a resident assessment tool that facilities are required to complete and submit to CMS for every resident in a Medicare and/or Medicaid certified nursing care facility. The MDS data serves as the basis for resident care planning and delivery of care, and it impacts the Medicare and Medicaid payment rates and CMS quality monitoring activity. As of 2017, CMS has integrated an evaluation of the MDS into the standard survey process.

Nurse Aide Registry

The Nurse Aide Registry is federally mandated, and its purpose is two-fold. The registry is to ensure the safety and well-being of nursing care facility residents across the state and to ensure other state registries are aware of annotated nurse aides in Pennsylvania. The Department maintains the state's registry, which as of June 30, 2019, has 327,056 nurse aides, 95,354 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

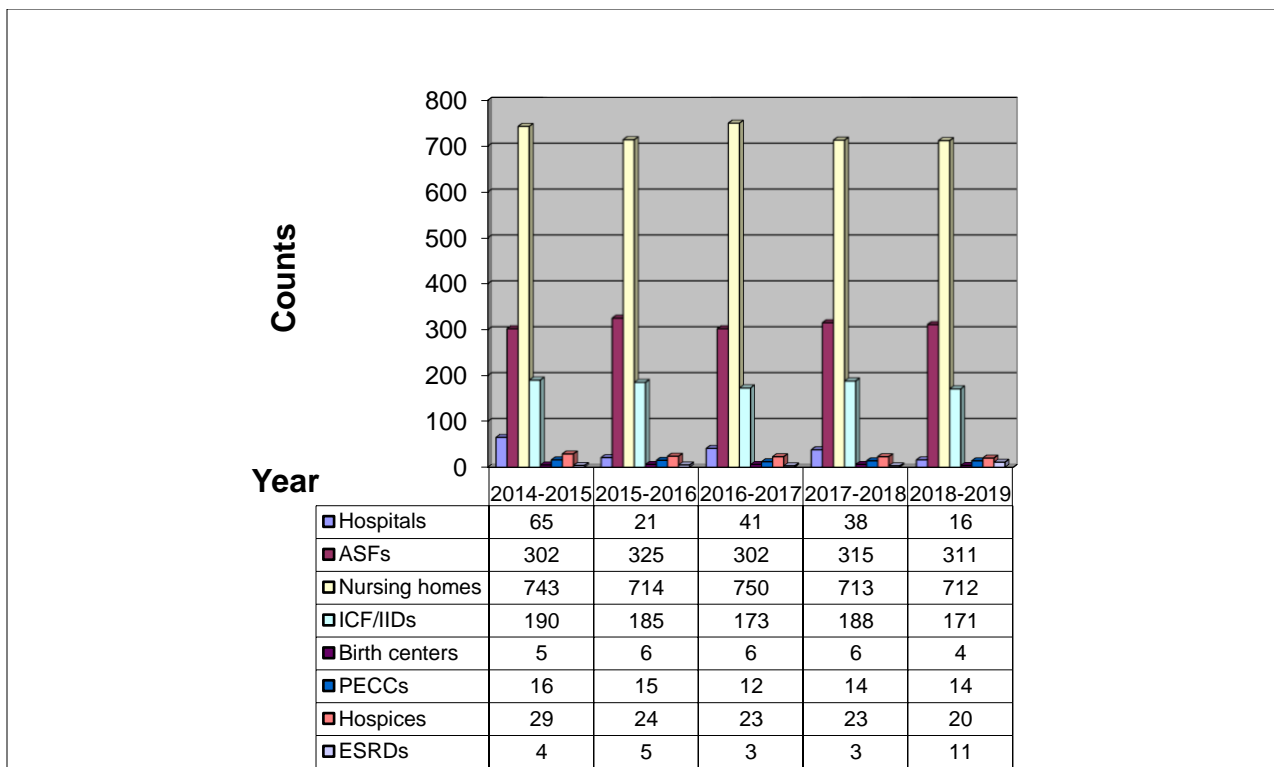
During SFY 2018-19, the Department performed 1,259 Life Safety Code surveys and 947 Life Safety Code revisits for hospitals, ASFs, nursing care facilities, birth centers, intermediate care facilities, ESRDs (dialysis centers), hospices and PECCs. The Department performed six new Medicare validation surveys and three Medicare validation revisit surveys.

The Department also performed Fire Safety Evaluation System (FSES) surveys for 267 health care building components. All surveys to verify compliance, or substantial compliance in the case of nursing care facilities, are unannounced. An exception to this can be given for non-long-term care facilities, other than HHAs, that meet the criteria listed in Section 2700A of the State Operations Manual.

The Department also reviewed 2,610 plans for construction or renovation of health care facilities. Of these plans, 1,782 met safety standards and were approved. These projects represent \$3,620,364,810 in construction costs. Plan reviewers are qualified by the Civil Service Commission based on their education and experience.

The Department performs a Life Safety Code occupancy inspection prior to use or occupancy of a newly constructed facility or a renovated space. During SFY 2018-19, the Department's Division of Safety Inspection (DSI) staff performed 1,037 occupancy inspections and 182 preoccupancy surveys. The Department's Safety Inspection staff conducted 3,257 surveys during SFY 2018-19. The number of surveys by facility type for the past five years is displayed in Figure 14.

Figure 14. Life Safety Code Surveys by Facility Type



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Enforcement Actions

The Department is authorized by the Health Care Facilities Act of 1979, P.L. 130, No. 48 (HCFA) and 28 PA Code §51.41 to sanction health care facilities that do not rectify serious violations of the act. Each facility is required to develop and submit a plan of correction (POC) that addresses violations identified by health or life safety surveys. The Department may sanction a facility in instances where it fails to submit an acceptable POC or (upon a follow-up survey) the facility continues to be found in violation of health or life safety standards.

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.

Table 2. Sanctions of Health Care Facilities, FY 18-19, by Facility Type

Facility Type	Sanctions	Total Sanctions
Nursing care facilities	Provisional licenses only	10
	*Provisional licenses with a civil monetary penalty	4
	Civil monetary penalty only	29

	Temporary managers placed	2
	Ban on admissions	0
	NCF TOTAL	45
ASFs	Provisional licenses only	10
	Provisional licenses with a civil penalty	0
	Civil penalty only	2
	Ban on admission	0
Hospitals	Provisional licenses only	2
	Provisional licenses with civil penalty	1
	Civil penalty only	4
	Ban on admissions	0
Home health agencies	Provisional licenses, each with a civil monetary penalty	9
Home care agencies	Provisional licenses, each with a civil monetary penalty	18
Hospices	Provisional licenses, both with a civil monetary penalty	3
PECCs	Provisional licenses, both with a civil monetary penalty	2
ICF/IDs	90-day termination actions	9
	OTHER FACILITIES TOTAL	63

*Note: Provisional licenses with a civil monetary penalty are counted as 2 sanctions. (For the information above there were 9 sanctions for the provisional licenses and 9 sanctions for the civil monetary penalties, totaling 18 sanctions.)

Source: Quality Assurance Survey Agency Information System (SAIS), 219

Additional Quality Assurance Activities

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

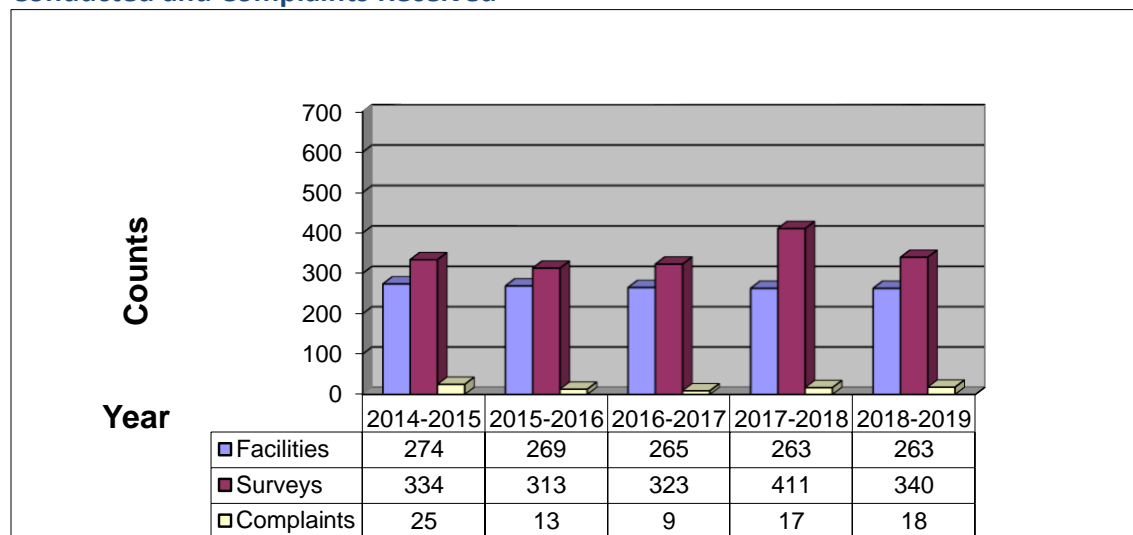
The Department ensures the health, safety and welfare of residents in 170 intermediate care facilities for individuals with intellectual and developmental disabilities (ICFs/IID) and individuals with other related conditions (ICFs/ORC). Legal authority for the Department's regulatory activities is derived from Title XIX of the Social Security Act (Medicaid) and the Life Safety Code. The Department has similar oversight of 79 psychiatric residential treatment facilities (PRTFs) for individuals under age 21. Both facility types are inspected for compliance with federal certification standards for participation in the state Medicaid program 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 investigations pertain to abuse, neglect, mistreatment, substandard care, misappropriation of funds, and other related health and safety issues. Onsite investigations of complaints that impact resident health or safety are a high priority. The Department conducted 340 facility surveys and investigated 18 complaints during SFY 2018-19. There were also 21 revisits. Figure 16

displays the survey and complaints information along with the number of Intermediate Care and Psychiatric Residential Treatment Facilities over the past five years.

The Department provides the ICF survey certification outcome information for the federal programs under Title XIX to the Department of Aging and the 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 Department of Human Services, Bureau of Program Integrity, with the survey certification outcome for PRTFs.

Figure 16. Number of Intermediate Care and Residential Treatment Facilities Surveys Conducted and Complaints Received



Source: Quality Assurance Survey Agency Information System (SAIS), 2019

Community Mental Health Centers (CMHC)

The Department assumed the survey responsibility for community mental health centers (CMHCs) during the SFY 2014-15. Prior to that, CMS surveyed these facilities for compliance. CMHCs are surveyed for Medicare certification.

Other Medicare Certified Programs

The Division of Home Health conducts Medicare recertification surveys every three years for 327 renal dialysis centers. Other programs certified by the Home Health Division every six years include: comprehensive outpatient rehab facilities (CORF) – 15, physical/speech therapists (OPT) – 91, and rural health centers (RHC) – 73.

Indoor Tanning Facilities

The Indoor Tanning Regulation Act, Act 41 of 2014, took effect on July 7, 2014, providing for the regulation of indoor tanning facilities and establishing the Indoor Tanning Regulation Fund. The act requires the Department of Health to register indoor tanning facilities. An indoor tanning facility is defined as any place where a tanning device is used for a fee, membership dues or any other compensation. Facilities operating tanning equipment or devices must register with the Department of Health on an annual basis. As of June 30, 2018, 398 facilities registered with the Department of Health.

Healthcare Associated Infection Prevention (HAIP)

The HAIP section was established to execute the Department'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 performed periodically. Onsite 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 onsite 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, web collaborations and targeted assessment for prevention reports are used to educate hospital infection prevention staff on the requirements of Act 52 of 2007, the CDC's National Healthcare Safety Network (NHSN) criteria and provide targeted data to hospitals with the greatest need for improvement. This is done to promote consistent reporting among hospitals.

Nursing care facilities began reporting infections into the Pennsylvania Patient Safety Reporting System (PA-PSRS) in June 2009. The Department reviews this data and provides nursing care facilities with individualized facility data verification reports to allow a facility to correct problems that may exist with their data and to help facilities ensure that the information regarding infections reported to PA-PSRS is accurate and dependable.

Outreach telephone calls are also made to nursing care facilities to review the updated infection reporting criteria released in April 2014 and to educate new staff on the requirements of Act 52 of 2007. Additional strategies have been implemented to promote consistent reporting in nursing care facilities, as well as to address the high turnover rate. The HAIP has engaged nursing homes to participate in the Infection Control Assessment and Response (ICAR) Program developed by the CDC. This new program focuses on assessing infection prevention practices and guiding quality improvement activities by addressing identified gaps with the goal of improving resident outcomes.

National Precursor Log Exchange (NPLEx)

The Pennsylvania Department of Health is responsible for the implementation of Act 53 of 2013. This law requires all Pennsylvania 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.

To comply with Act 53, the Commonwealth of Pennsylvania joined the National Precursor Log Exchange (NPLEx). Pharmacies and retailers in the commonwealth are provided, at no charge, access to a web-based database provided by Appriss where they can enter PSE sales data 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, inspections, and compliance of Pennsylvania-based manufacturers and compounders/distributors/wholesalers and retailers of any drugs, medical devices and equipment, medical gases, and medicated cosmetics. Licensure is required of human prescription drug wholesale distributors. Table 3 lists the number of registrants and licensees by type. The program is also responsible for administrative duties related to the scheduling and handling of controlled substances, distribution of List I chemicals and equivalencies related to generic drug/brand drug substitutions. 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, nonprescription drugs and adulterated products are investigated and handled as well.

Table 3. Number of DDC Program Registrants by Type, Fiscal Year 2018-2019

Type	No. of Registrants
Manufacturer (prescription)	616
Manufacturer (non-prescription)	92
Distributor (prescription)	1160
Distributor (non-prescription)	428
Retailer (non-prescription)	7486
Devices	2467
Wholesaler/distributor licenses	312
Other (nonresident, List I, etc.)	529
Total	13090

Source: DDC Application Access Database, 2019

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. Table 4 lists the number of registrants by type. 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

Table 4 . Number of Hearing Aid Program Active Registrants by Type, Fiscal Year 2018-2019

Type	No. of Registrants
Fitters	506
Dealers	416
Apprentice fitter	77
Temporary fitters	2
Branches – dealer	571
Total	1594

Source: Hearing Aide Application Access Database, 2019

Table 5. Sanctions of DDC Program and Hearing Aid Program

Registration/License Type	Sanctions	Total Sanctions
Hearing aid fitter	Revocation of registration	2
Wholesale drug distributor	Warning letter	1
Wholesale drug distributor	Revocation of license; Voluntarily submitted	1

Source: Program Manager DDC and Hearing Aid Program/Database and Legal Cou

References

Quality Assurance Survey Agency Information System, 2018. Pennsylvania Department of Health.

Program Manager DDC and Hearing Aid Program Database, 2018. Pennsylvania Department of Health.