

# Report of the Quality Assurance Programs

Report for State  
Fiscal Year 2023-  
2024



**pennsylvania**  
DEPARTMENT OF HEALTH

## Contents

Introduction	3
Health Care Facility Survey and Certification Program	3
Ambulatory Surgical Facilities	5
Birth Centers	6
Home Health Care Agencies	7
Home Care Agencies and Registries	8
Hospices	9
Pediatric Extended Care Centers	10
Hospitals	11
Patient Safety Activities and Reporting	13
Nursing Care Facilities	14
Nurse Aide Registry	17
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) and Psychiatric Residential Treatment Facilities (PRTF)	18
Community Mental Health Centers (CMHC)	19
Influenza and Pneumonia Immunization Information	19
Safety Inspection	20
Enforcement Actions	21
Other Medicare Certified Programs	23
Indoor Tanning Facilities	23
Drug, Device, and Cosmetic Program	23
Hearing Aid Program	24
Temporary Health Care Services Act Program General Report	26
Mother's Milk Banks	26

## 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 Long-Term Care Programs, Health Facilities and Home Care Services, and Finance and Administration. The Act defines a health care facility as a general, chronic disease or other type of hospital; a home health care agency; a home care agency; a hospice; a long-term care nursing facility; an ambulatory surgical facility; and a birth center—regardless of whether such health care facility is operated for profit, nonprofit or by an agency of the Commonwealth or local government. 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. Act 128 of 2022 amended the Act, providing for the registration and regulation of temporary health care services agencies.

In addition to the licensure functions for health care facilities as defined in the Act, the Department also oversees Pediatric Extended Care Centers; Indoor Tanning Facilities; Drugs, Devices and Cosmetics; the Hearing Aid Program; Temporary Health Care Staffing Agencies; and Mother’s Milk Banks. These programs are described in more detail in later sections.

Additionally, the Department serves as the state survey agency, certifying facilities for the Centers for Medicare and Medicaid Services (CMS). Licensure permits a health care facility to operate in Pennsylvania. Certification permits a facility to claim and receive payment for services rendered under the Medicare and Medicaid programs. The Department performs CMS certification functions for nearly all of the health care facility types it licenses, including hospitals, home health care agencies, hospices, long-term care nursing facilities, and ambulatory surgical facilities, as well as several other facility types, including intermediate care facilities for individuals with intellectual disabilities, psychiatric residential treatment facilities, community mental health centers, renal dialysis centers, outpatient rehabilitation facilities, outpatient physical therapy and speech pathology services, and rural health centers.

This report contains information on the above-described health care facilities and other regulated facilities and entities for the state fiscal year (SFY) 2023-2024. Additional information can be found on the health care facility pages on the Department’s website.

### Health Care Facility Survey and Certification Program

In performance of its state licensure of health care facilities and CMS certification functions, the Department conducts both routine and special inspections 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/or certification, the Department notifies the facility in a statement of deficiencies. Facilities are required to submit a plan of correction (POC) in response to the statement of deficiencies. The POC is mandatory and is the means by which the Department monitors and ensures correction of deficiencies. Generally, as long as the facility submits an acceptable POC, it may continue to operate and receive Medicare and Medicaid payments while deficiencies are being corrected.

The Department maintains a staff of approximately 250 trained surveyors (health care surveyors, health care nurse surveyors, and safety inspectors) to perform these licensure and certification functions. Most health care 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 regular, ongoing training to all surveyors to ensure they maintain current knowledge and thorough understanding of applicable state and federal regulations 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.

In some instances, accreditation organizations perform licensure and/or certification surveys instead of the Department. For CMS certification, hospitals, home health care agencies, and ambulatory surgical facilities can be granted “deemed” status, which means the facility has been surveyed by a CMS-approved accrediting organization and was determined to be in compliance with the applicable federal regulatory standards. Deemed facilities are exempt from Medicare recertification surveys by the state agency and are under the jurisdiction of the CMS-approved accreditation program for continued federal compliance oversight. For state licensure, only hospitals can rely on the reports of accreditation organizations in lieu of a state licensure survey by the Department.

In addition to licensure and certification functions, as part of its quality assurance and patient safety responsibilities, and in accordance with 28 Pa. Code Chapter 51, the Department tracks events reported by licensed health care facilities (except hospital, ambulatory surgical facilities, birth centers, and abortion facilities) through a mandatory web-based Electronic Event Reporting System (ERS). The ERS enables health care facilities to submit, review, and analyze reported events and supports facility-level quality improvement activities, performance

monitoring, and the Department's oversight of patient safety trends across care settings. Department staff review facility reports in the ERS and based upon assessment of the actual or potential effect on resident or consumer health and safety, determine the need for immediate on-site investigation or integration into other survey activities. Patterns found in the assessment of the event reports alert staff to issues affecting resident or consumer safety, thereby helping to improve safety and to focus future survey activity. Hospitals, ambulatory surgical facilities, birth centers and abortion facilities report similar information through the PA-Patient Safety Reporting System, as described in the Patient Safety Activities and Reporting section below.

### **Ambulatory Surgical Facilities**

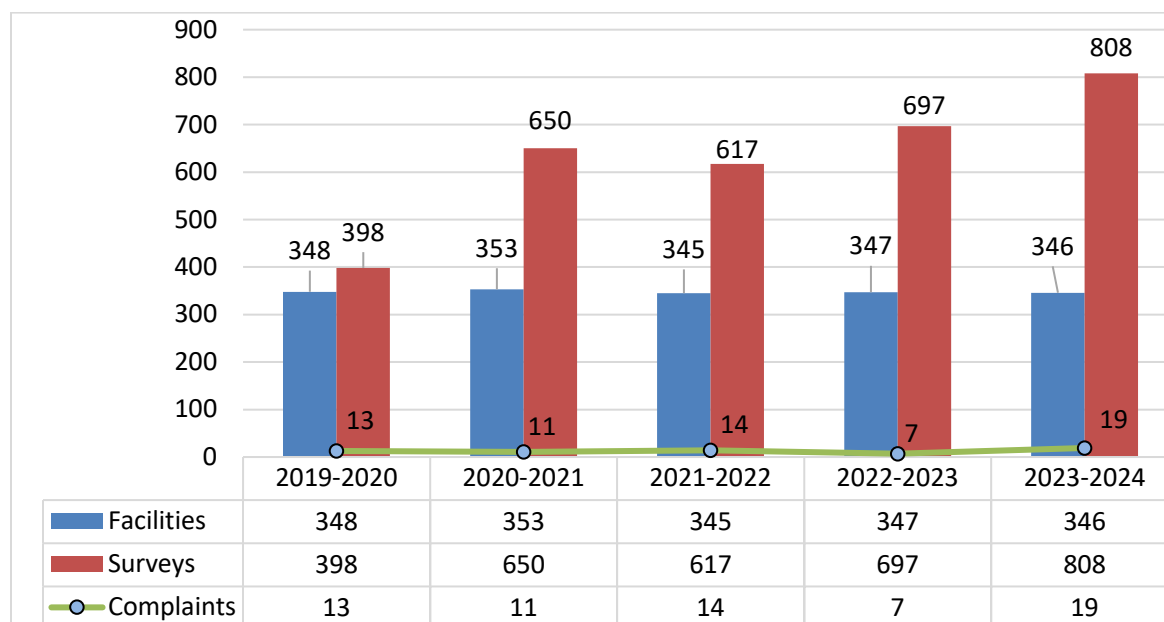
As of June 30, 2024, there were 346 ASFs licensed or registered in Pennsylvania, a decrease of 1 ASF over the previous SFY. Abortion facilities are included in these counts. ASFs are classified as A, B or C based on procedures performed, patient status, and anesthesia used. Class A facilities register annually with the Department but are not licensed.

Class B and Class C ASFs licenses must be renewed on an annual basis. The license renewal process includes an announced on-site survey. If found to be out of compliance with the licensure regulations, ASFs must develop and submit POCs 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 23-24 SFY. In addition, it conducted 327 licensure and certification surveys, 235 occupancy surveys, and 170 revisits for ASFs in the 23-24 SFY, representing a decrease of 9 licensure and certification surveys and 5 revisits, and an increase of 105 occupancy surveys 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 Table 1.

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



Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

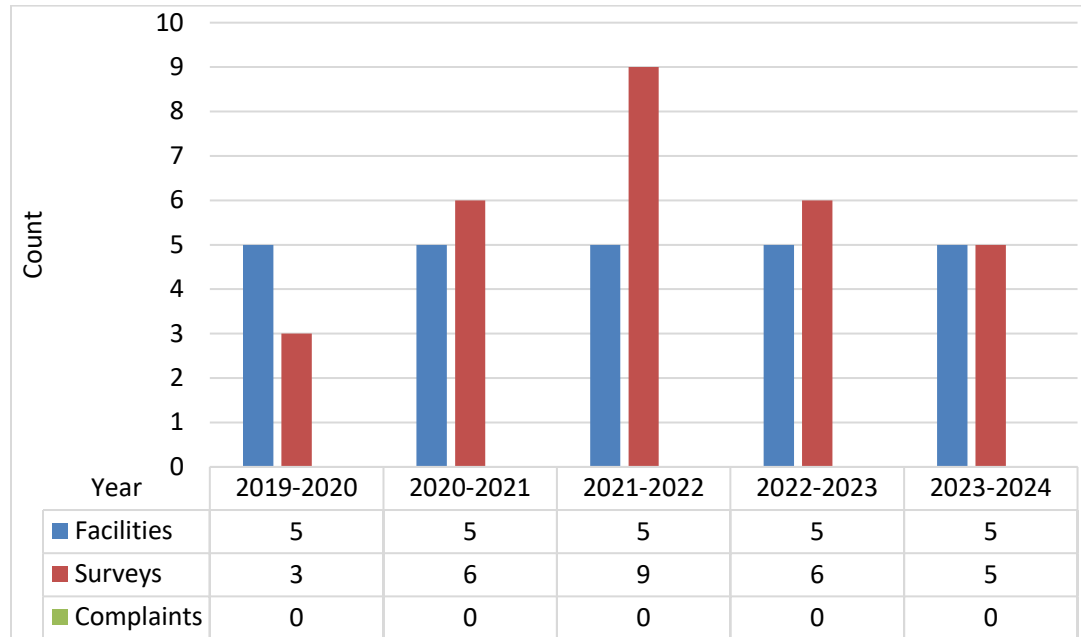
**NOTE:** Surveys count includes certification and licensure surveys, complaint surveys, revisit surveys, occupancy surveys, and special monitoring surveys, unless otherwise indicated.

### Birth Centers

There are five licensed birth centers in the Commonwealth. Birth centers provide care before, during and after delivery to patients who are low-risk for pregnancy-related complications. 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 period.

The number of birth centers, all surveys conducted, and complaints received 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 Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

### Home Health Care Agencies

Home Health Care Agencies (HHA) must be licensed by the Department and must provide part-time, intermittent skilled nursing services plus at least one other therapeutic service (physical therapy, occupational therapy, speech pathology, medical social services or home health aides) to individuals in their homes or other independent living environments. Licensure surveys are required prior to the provision of services.

During this reporting period, there were 601 licensed HHAs operating in the Commonwealth, a decrease of 31 agencies from the previous reporting period. CMS certified 397 HHAs based upon the Department’s recommendation. The remaining 204 HHAs are state licensed only because they chose not to participate in the federal reimbursement programs. The Department conducted 171 Medicare and/or state licensure on-site surveys in the 23-24 SFY.

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 a 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

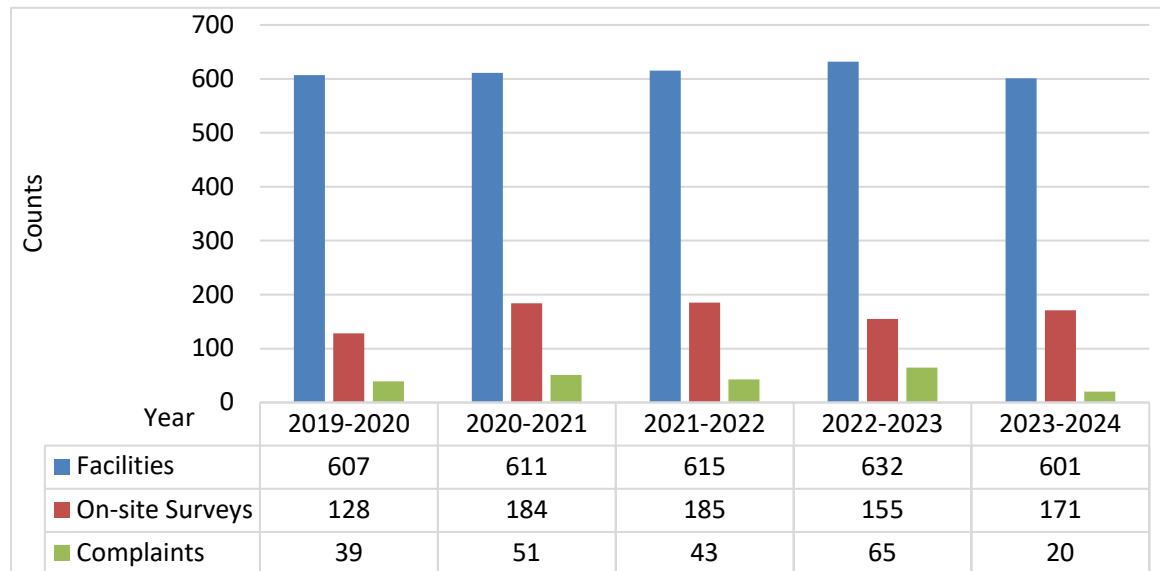
survey is based on written documentation of compliance with licensure requirements, attested to by the agency administrator as correct and submitted to the Department for review.

During the 23-24 SFY, the HHAs survey schedule was one on-site survey and two off-site 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 20 HHA complaints during the 23-24 SFY, a decrease of 45 complaint investigations from the previous SFY.

The number of HHAs, Licensure and Certification on-site surveys and complaints over the last five years are displayed in Figure 3.

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



*Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.*

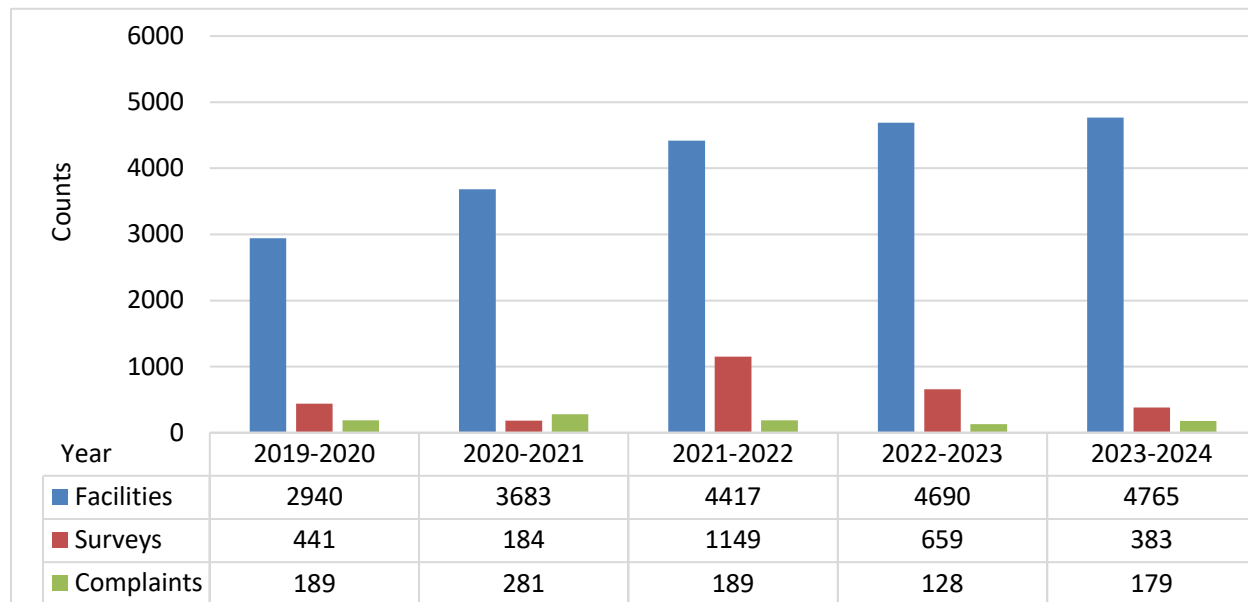
### Home Care Agencies and Registries

Home care agencies and home care registries provide non-skilled services to individuals in their homes or other independent living environments. Home care agencies supply, arrange or schedule employees to provide home care services. Home care registries supply, arrange or refer independent health care 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 and registries are surveyed within nine months after initial licensure. Only those home care agencies and registries serving three or more clients are surveyed.

Over the last year, the number of home care agencies and registries increased by 75 from 4,690 to 4,765. The five-year growth rate for home care agencies and registries is approximately 62 percent. The number of home care agencies and registries, surveys conducted, and complaints are displayed in Figure 4

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



*Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.*

### Hospices

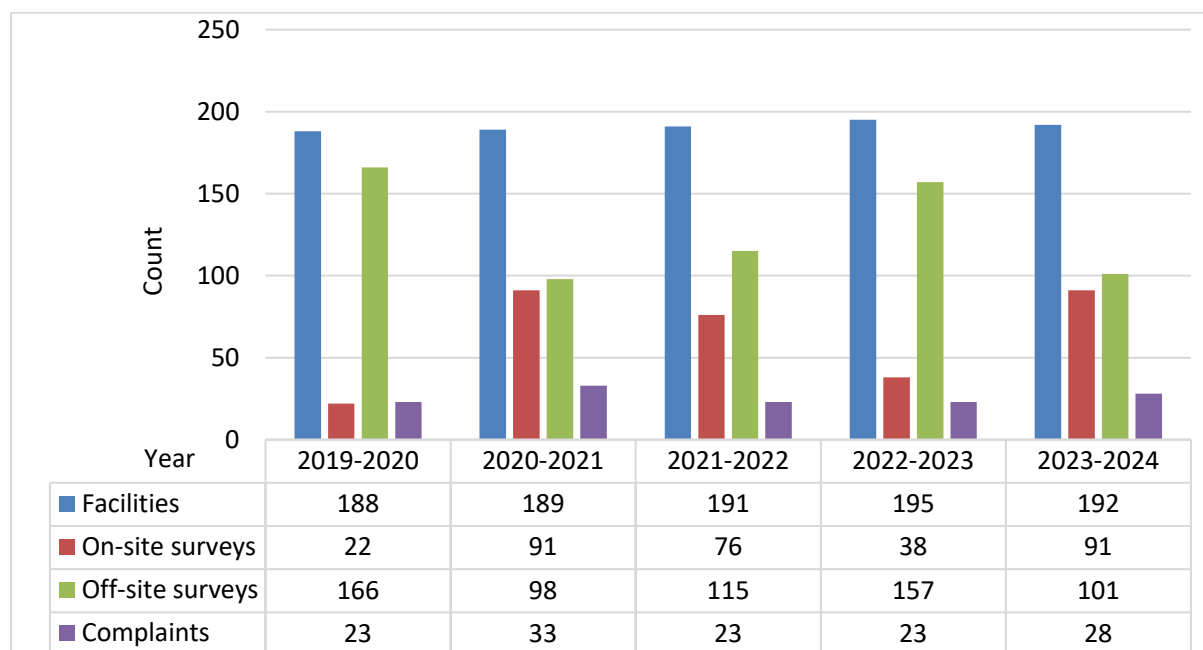
Hospices provide medical care, pain management and emotional and spiritual support for patients who are nearing the end of life and their families. Hospice care uses a team-oriented approach expressly tailored to the patient's needs while supporting their quality of life.

The Department uses Medicare standards to license hospices. There are currently 192 hospices that are licensed and Medicare-certified. There are no hospices that are state licensed only. The federal Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 mandates surveys of Medicare certified hospices occur no less frequently than every 36 months.

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 accurate and submitted to the Department for review. In the 23-24 SFY, the Department surveyed 91 hospices on-site, and 101 were licensed through off-site surveys.

The number of hospices, on-site and off-site surveys conducted, and complaints received for the past five years are displayed in Figure 5.

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

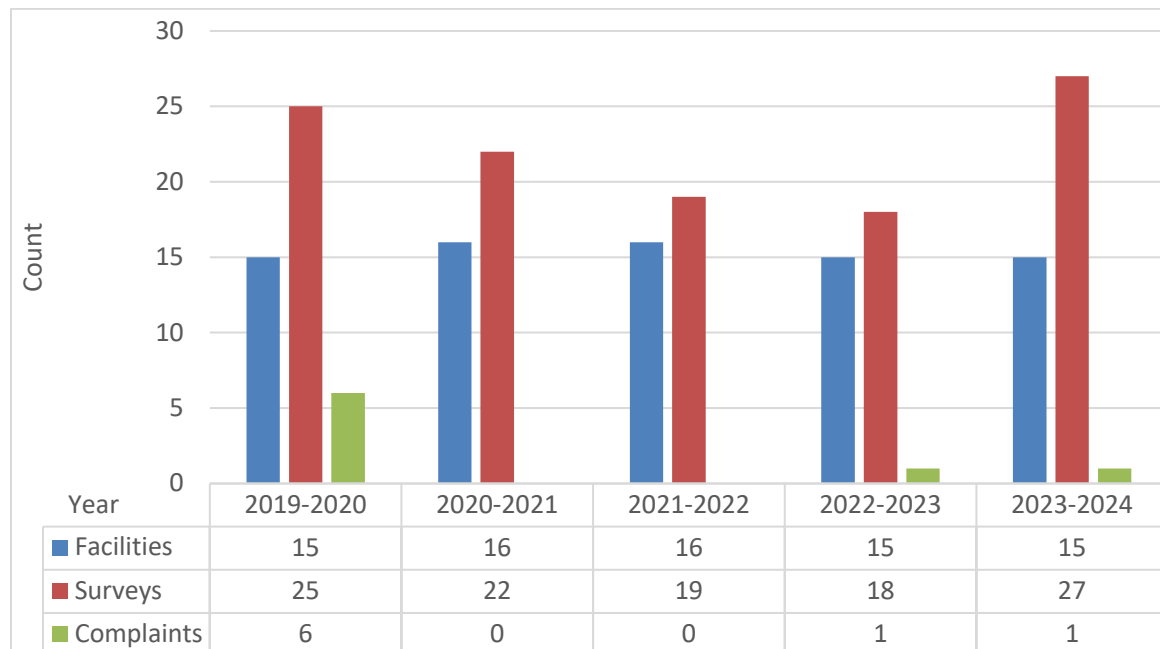


Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

### Pediatric Extended Care Centers

Pediatric Extended Care Centers (PECCs) are non-residential childcare facilities staffed by nurses and therapists who provide day care and clinical intervention to medically dependent or technologically dependent children. The Department is authorized to license, inspect, and sanction PECCs under the Prescribed Pediatric Extended Care Centers Act (PECC Act), 35 P.S. §§ 449.61-449.77. PECCs do not provide 24-hour care, and the children do not stay overnight in the facility. The goal of the PECC is to provide comprehensive and coordinated care to benefit children’s families. 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 111 of 2012, which amended the PECC Act, increased the PECC service eligibility age from 8 to 21 years. PECCs are licensed annually using an unannounced, on-site survey. During the 23-24 SFY reporting period, there were 15 PECCs licensed in the Commonwealth. The Department received one complaint regarding the care and services provided by PECCs. Figure 6 demonstrates the number of PECCs, 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 Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.*

### Hospitals

The Department conducts state licensure surveys of hospitals, including general acute care hospitals, other specialty hospitals, rehabilitation hospitals, children’s hospitals, long-term acute care hospitals, and critical access hospitals. The Department does not license federal VA Medical Centers because they are licensed by the federal government. Psychiatric hospitals are licensed by the Pennsylvania Department of Human Services.

As of June 30, 2024, the Department licensed 138 acute care hospitals (which includes other specialty hospitals), 18 rehabilitation hospitals, 5 children’s hospitals, 12 long-term acute care hospitals, and 16 critical access hospitals, for a total of 189 licensed hospitals. In total, there are 251 hospital campuses operated by the 189 licensed hospitals. A hospital campus operates as an off-site location under a hospital license and generally offers inpatient and outpatient services but is located at a different address than the main licensed hospital. Additionally, the 189 hospital licenses extend to 2,268 outpatient locations for which the Department has regulatory oversight.

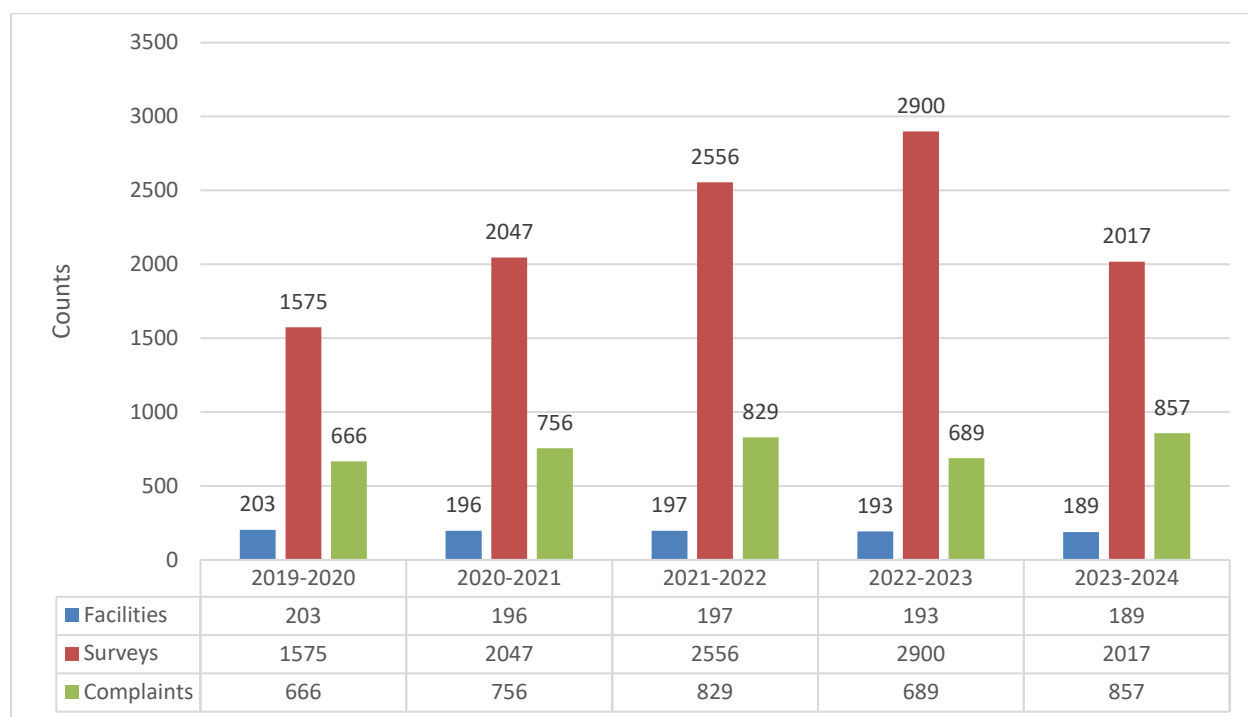
During the 23-24 SFY, the Department renewed 125 hospital licenses. The Department completed 35 licensure and certification surveys, 771 occupancy surveys, and 217 revisits,

representing a decrease of 5 licensure and certification surveys, 922 occupancy surveys, and 42 revisits over prior SFY.

The Department received a total of 857 complaints related to hospitals during this reporting period, an increase of 168 complaints over the prior SFY.

The numbers of licensed hospitals, surveys and complaints over the last five years are displayed in Figure 7. Additional information about serious events and infrastructure failures reported by hospitals is provided in Table 1.

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



Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

**NOTE:** Survey count includes licensure and certification, complaint, 5100 (Psychiatric Unit), attestation validation, occupancy, special monitoring, and revisit surveys unless otherwise indicated.

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. Seventy-nine hospitals chose this option for the 23-24 SFY. 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.

## Patient Safety Activities and Reporting

Act 13 of 2002 delegated specific responsibilities for the Department in implementing the Patient Safety Act (PSA). The initial survey procedure includes review and approval of the Patient Safety Plans required by Act 13 for newly licensed facilities. 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 PSA, the Department collects an 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 by the PSA in the collection and analysis of patient safety information. In the 23-24 SFY, \$7,796,659.75 was collected.

The Department also receives, reviews and responds to patient safety-related occurrences reported by hospitals, ASFs, and birth centers in the PA Patient Safety Event Reporting System. 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 undesirable or unintended events, occurrences or situations that affect the infrastructure (i.e., physical plant and service delivery systems) of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

During the 23-24 SFY, ASFs reported 2,553 serious events and infrastructure failures to the Department, a decrease of 11 from the prior year. Hospitals reported 109,428 serious events and infrastructure failures, an increase of 298 reports over the prior SFY. All serious events and infrastructure failure reports are reviewed by division staff, and on-site investigations are conducted as appropriate. Hospital, ASF, and birth center specific data for the past three years are displayed in Table 1.

**Table 1. Serious Events and Infrastructure Failures by Facility Type**

<b>Fiscal Year</b>	<b>2021-2022</b>	<b>2022-2023</b>	<b>2023-2024</b>
Hospital serious events	7,351	8,828	10,262
Hospital other events	793	702	760
Hospital infrastructure failures	92,436	99,600	98,406
ASF serious events	1,987	2,047	1,978
ASFs infrastructure failures	599	517	575
Birth centers serious events	1	5	7
Birth centers infrastructure failures	1	2	2

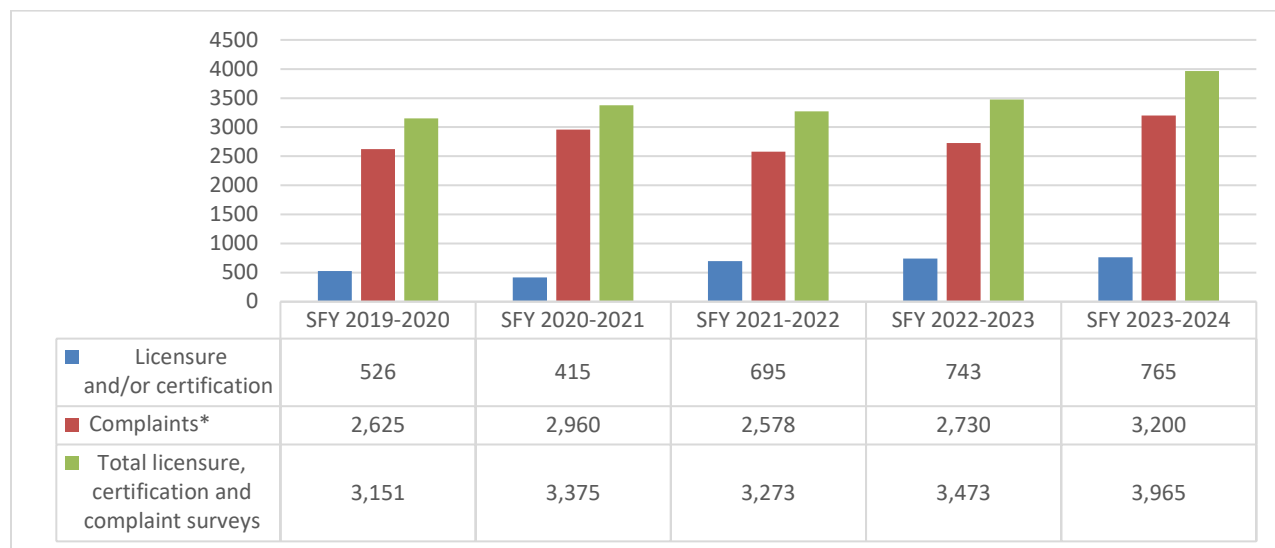
*Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.*

### **Nursing Care Facilities**

As of June 30, 2024, there were 670 nursing care facilities licensed in Pennsylvania, providing services to 85,124 short and long-term care residents. These facilities are surveyed for annual licensure on a variable schedule. All on-site 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 22 occupancy surveys of nursing care facilities during the SFY.

The numbers of nursing care facility licensure/certification surveys and complaints are displayed in Figure 8.

**Figure 8. Nursing Care Facility Surveys Completed in the 19-24 Fiscal Years**



Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

**\*NOTE:** The number of complaints depicts the number of surveys completed due to complaints received. There were 5,870 complaints received in the 23-24 SFY, although multiple complaints could be investigated in a single survey.

During the 23-24 SFY, the most frequent deficient practices cited during the reporting period, were: 1) Nursing services; 2) Quality of Care; 3) Food Procurement, Store/Prepare/Serve-Sanitary; 4) Free of Accident Hazards/Supervision/Devices; 5) Infection Prevention & Control; and 6) Develop/Implement Comprehensive Care Plan.

The federal government provides states with awards funding to assist with the cost of nursing care facility survey initiatives. To receive the awarded 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 funding provides for on-site semi-annual certification, monitoring visits, and complaint investigations.

The Department investigates all complaints regarding the care of nursing care facility residents. When multiple complaints are received regarding the same facility, they may be investigated during the same survey for added efficiency, or they may be investigated at a separate time. The majority of complaints are investigated through on-site visits. However, off-site 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 the 23-24 SFY, 99 percent of complaints were investigated on-site.

Complaints are received from various sources including hotline calls, communications to the central office and field offices, referrals from other agencies, and via the Department's website. Additional sources include the Governor's Hotline, the Attorney General's Office, legislators' offices, emails submitted to a designated complaint email address, and residents and their families speaking directly to surveyors during an on-site 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 nursing home residents. Sometimes issues are identified in the complaint process that are not under the jurisdiction of the division. In these instances, referrals are made to other Department offices, state agencies or local authorities as appropriate.

During the 23-24 SFY, the Department received 5,870 complaints. All complaints are prioritized according to federal regulations. 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 three business days. Complaints that are not IJ priority are prioritized using the classifications below. Deadlines for those priorities establish the days permitted from complaint receipt to onsite investigation initiation. Offsite investigation deadlines establish the number of days from complaint receipt to investigation completion:

Non IJ High – 15 business days

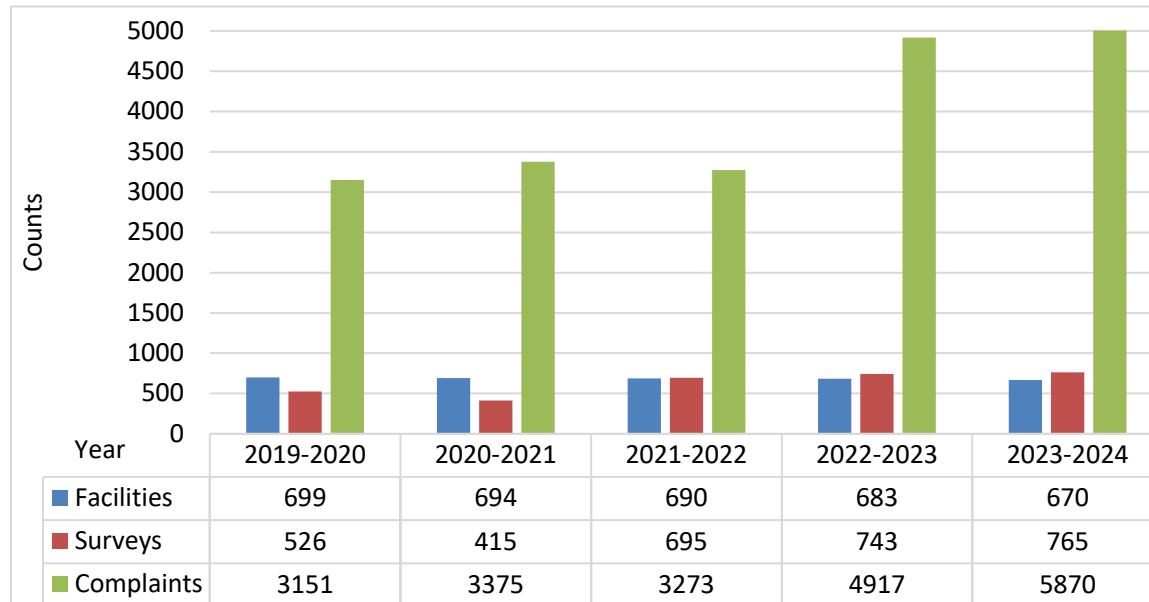
Non IJ Medium – 45 calendar days

Non IJ Low – 120 calendar days

Offsite investigation – 30 calendar days

The number of facilities, surveys and complaints for the past five years are displayed in Figure 9.

**Figure 9. Number of Nursing Care Facilities, Licensure and/or Certification Surveys Conducted and Complaints Received**



*Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.*

As mentioned in the Health Care Facility Survey and Certification Program section, nursing care facilities certain events into ERS. , During the 23-24 SFY, 65,147 events were reported; this was a decrease of 11,592 events from the prior SFY.

### **Nurse Aide Registry**

Nursing care facilities have the responsibility to employ qualified nurse aides who are properly trained, and have no substantiated findings against them of abuse, neglect, exploitation or misappropriation of property. The Nurse Aide Registry is mandated by Federal law, and its purpose is two-fold: (1) to ensure the safety and well-being of nursing care facility residents across the state, and (2) to assure that nursing care facilities hire only nurse aides who do not have substantiated findings against them. The Department maintains the state’s registry, which as of June 30, 2024, has 374,102 nurse aides, 81,814 of whom are active. Inactive nurse aides include individuals whose registration has lapsed and nurse aides who have been annotated. Annotated nurse aides are those with substantiated findings of abuse, neglect, exploitation, or misappropriation of resident property. It is the responsibility of the nursing care facility to check the status on the registry of any nurse aide it is intending to hire to confirm eligibility.

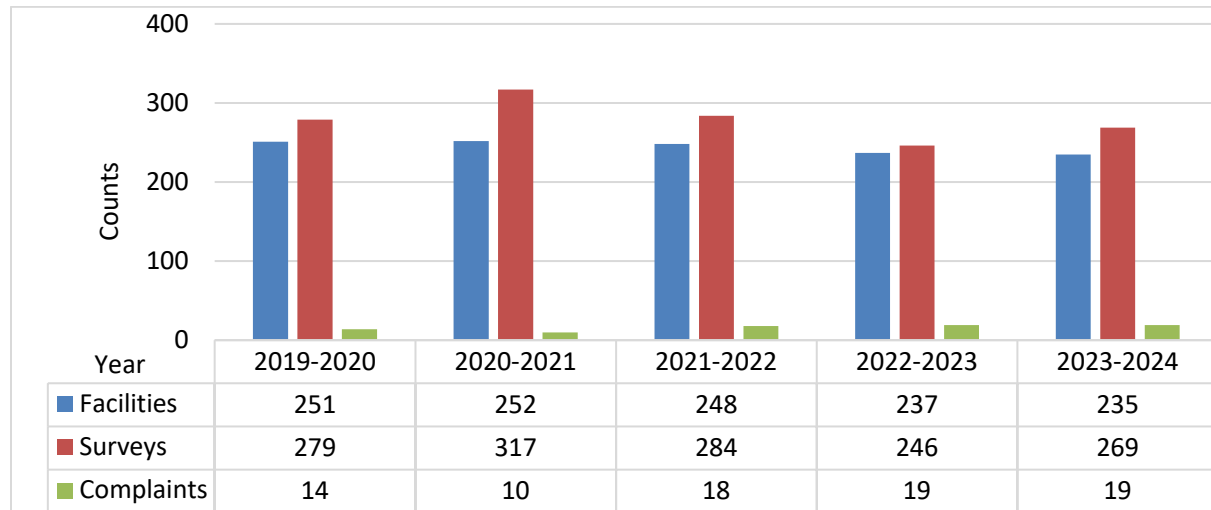
## **Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) and Psychiatric Residential Treatment Facilities (PRTF)**

The Department ensures the health, safety and welfare of residents in 156 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 of the National Fire Prevention Association. 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 standards.

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. On-site investigations of complaints that impact resident health or safety are a high priority. The Department conducted 269 facility surveys and investigated 19 complaints during the 23-24 SFY. There were also 11 revisits. Figure 11 displays the survey and complaints information along with the number of ICFs and PRTFs 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 11. Number of Intermediate Care and Residential Treatment Facilities Surveys Conducted and Complaints Received**



Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

### Community Mental Health Centers (CMHC)

The Department assumed the survey responsibility for Community Mental Health Centers (CMHCs), which provide mental health services to individuals who require the services of a partial hospitalization program, during the 14-15 SFY. Prior to that, CMS surveyed these facilities for compliance. CMHCs are surveyed for Medicare certification on a 5-year cycle. There is currently one CMHC in the Commonwealth.

### Influenza and Pneumonia Immunization Information

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. Table 2 provides the data for influenza virus and pneumococcal disease for the past four years.

**Table 2. Influenza and Pneumonia Immunization Information, 2020-2024**

SFY	2020-2021	2021-2022	2022-2023	2023-2024
<b>Influenza</b>				
Outbreaks due to Influenza Virus	65	207	535	505
Hospital admissions for flu symptoms	231	218	294	360
Hospital admissions for confirmed flu	18	37	139	225
Hospital admissions for flu complications	125	107	191	195
<b>Pneumococcal</b>				
Outbreaks of pneumococcal disease	357	417	606	305
Hospital admissions for pneumococcal disease	782	869	1,095	634
Hospital admissions for pneumococcal disease complications	412	406	458	388

*Source: Health Informatics Office, Statistical Support Team, Nursing Home Reports 2023-2024. Pennsylvania Department of Health.*

### **Safety Inspection**

During the 23-24 SFY, the Department’s Division of Safety Inspection (DSI) performed 1,284 Life Safety Code surveys and 980 Life Safety Code revisits for hospitals, ASFs, nursing care facilities, birth centers, intermediate care facilities, ESRDs (Dialysis Centers), hospices, and PECCs.

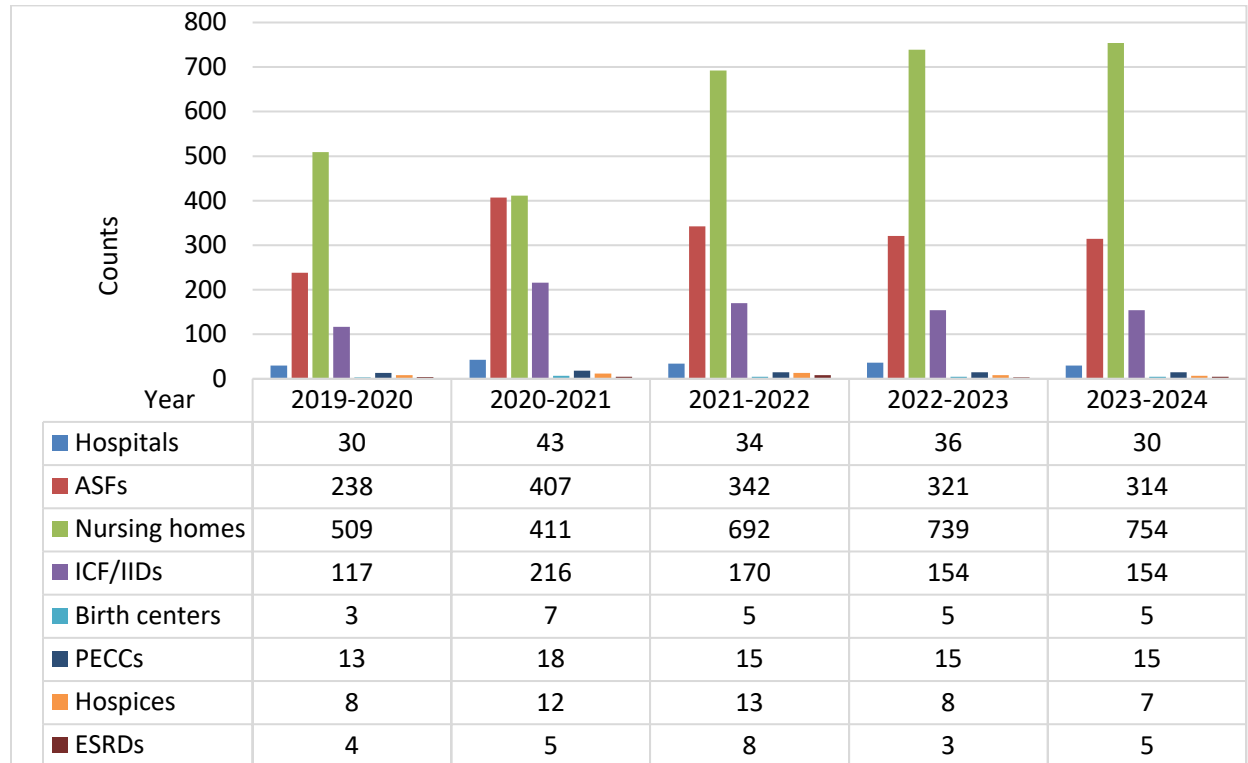
DSI also performed Fire Safety Evaluation System surveys for 267 health care building components. All surveys to verify compliance, are unannounced.

In accordance with 28 Pa. Code §51.3(d), DSI also reviewed 1,771 plans for construction or renovation of health care facilities. Of these plans, 1,144 met safety standards and were approved. These projects represent \$3,590,456,546 in construction costs. Plan reviewers are qualified by the Civil Service Commission based on their education and experience.

DSI performs a Life Safety Code occupancy inspection prior to use or occupancy of a newly constructed facility or a renovated space. During the 23-24 SFY, DSI performed 668 occupancy

inspections, 505 preoccupancy surveys, and 2,975 surveys. The number of surveys by facility type for the past five years is displayed in Figure 10.

**Figure 10. Life Safety Code Surveys by Facility Type**



*Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.*

### Enforcement Actions

The Department is authorized by the Act and 28 Pa. Code § 51.41 to penalize health care facilities for violations of the Act. Each facility is required to develop and submit a POC that addresses violations identified by health or life safety surveys. The Department may sanction facilities 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 set by the regulations and statutes governing each facility type.

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 3 provides the data relating to sanctions.

**Table 3. Sanctions of Health Care Facilities, SFY 23-24, by Facility Type**

<b>Facility Type</b>	<b>Sanctions</b>	<b>Total Sanctions</b>
Nursing care facilities	Provisional licenses only	7
	Provisional licenses with a civil monetary penalty	21
	Civil monetary penalty only	107
	Temporary managers placed	1
	Ban on admissions	3
	<b>NCF TOTAL</b>	<b>139</b>
ASFs	Provisional licenses only	2
	Civil monetary penalty only	3
Hospitals	Provisional licenses only	2
	Civil monetary penalty only	7
Home health care agencies	Provisional licenses only	2
	Provisional licenses with a civil monetary penalty	8
Home care agencies/registries	Provisional licenses only	7
	Provisional licenses with a civil monetary penalty	5
Hospices	Provisional licenses with a civil monetary penalty	2
	Civil monetary penalty only	2
Intermediate Care Facilities for Individuals with Intellectual Disabilities	90-day termination actions	9
	<b>OTHER FACILITY TYPES TOTAL</b>	<b>55</b>

Source: Quality Assurance Deputate, Survey Agency Information System, 2024. Pennsylvania Department of Health.

### **Other Medicare Certified Programs**

The Division of Home Health conducts Medicare recertification surveys every three years for 320 renal dialysis centers and every six years for 17 comprehensive outpatient rehab facilities, 97 outpatient physical therapy and speech pathology services, and 78 rural health centers.

### **Indoor Tanning Facilities**

The Indoor Tanning Regulation Act, Act 41 of 2014, took effect on July 7, 2014, providing for the registration of indoor tanning facilities and establishing the Indoor Tanning Regulation Fund. The Act requires the Department 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 using Ultra Violet radiation must register with the Department on an annual basis. As of June 30, 2024, 592 facilities are registered with the Department.

### **Drug, Device, and Cosmetic Program**

The Drug, Device and Cosmetic Program (DDC) oversees the Controlled Substance, Drug, Device, and Cosmetic Act and regulations, Non-Controlled Substances Reporting and Registration Act, Generic Drug Equivalency/Substitution Laws and regulations, and the Wholesale Prescription Drug Distributors License Act. 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. Wholesale distributors of human prescription drugs must secure a license and DDC monitors compliance through surveys and complaint investigations. Table 4 lists the number of registrants and licensees by type. DDC is also responsible for providing guidance related to the scheduling and handling of controlled substances, distribution of List I chemicals, and equivalencies related to generic drug/brand drug substitutions. DDC often partners with other federal and state agencies regarding the integrity of the United States drug supply. DDC also investigates and handles consumer complaints regarding retail sales of medical devices, nonprescription drugs, and adulterated products. \*Note: Act 101 of 2024 was signed on October 16, 2024, and mandates licensure of in-state virtual manufacturers by April 2025.

**Table 4. Number of DDC Program Registrants by Type, SFY 23-24**

Type	No. of Registrants
Manufacturer (prescription)	741
Manufacturer (non-prescription)	121
Distributor (prescription)	1125
Distributor (non-prescription)	370
Retailer (non-prescription)	6740
Devices	2655
Wholesaler/distributor licenses	236
Other (nonresident, List I, etc.)	466
Virtual manufacturer (certificate of record) *	56
Total	12510

*Source: Bureau of Health Facilities and Home Care Services, Program Manager, DDC and Hearing Aid Program Database, 2024. Pennsylvania Department of Health.*

### **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, apprentice fitters, and temporary fitters, as well as hearing aid dealers/sellers. Table 6 lists the number of registrants by type. The program qualifies new hearing aid fitters through the administration of a semi-annual examination. The Department has oversight of audiologists and physicians, limited to the fit, sales or distribution of hearing aids. The program also investigates and handles consumer complaints regarding hearing aids sales.

**Table 5. Number of Hearing Aid Program Active Registrants by Type, SFY 23-24**

Type	No. of Registrants
Fitters	506
Dealers	349
Apprentice fitter	38
Temporary fitters	5
Branches – dealer	572
Total	1470

Source: Bureau of Health Facilities and Home Care Services, Program Manager, DDC and Hearing Aid Program Database, 2024. Pennsylvania Department of Health.

The Department of Health maintains oversight and enforcement authority over individuals and entities registered under the Hearing Aid Program. This includes the ability to take disciplinary or corrective actions when violations of relevant laws or regulations are identified. Sanctions and enforcement actions may include, but are not limited to, denial of registration, issuance of warning letters, and other disciplinary measures. These actions are intended to ensure public protection, maintain industry standards, and encourage corrective compliance among regulated parties. For the SFY 23–24, as seen in Table 6, no sanctions or enforcement actions were taken against hearing aid fitters, wholesale drug distributors, or other registrants.

**Table 6. Sanctions/Legal actions of DDC Program and Hearing Aid Program**

Registration/License Type	Sanctions/Actions	Total Actions
Hearing aid fitter	Denial of registration reinstatement	0
Hearing Aid Fitter	Warning	0
Wholesale drug distributor	Warning letter	0

Source: Bureau of Health Facilities and Home Care Services, Program Manager, DDC and Hearing Aid Program Database, 2024. Pennsylvania Department of Health.

## **Temporary Health Care Services Act Program General Report**

On November 3, 2022, Act 128 of 2022 amended the Act requiring Temporary Healthcare Services Agencies (THCSAs) to be registered and regulated. THCSAs are defined as any person engaged for hire in procuring temporary employment in healthcare facilities for certain health care personnel (including nurse aides, registered nurses, licensed practical nurses, and direct care staff). Act 128 provides that any person who owns or operates a THCSA shall register annually with the Department and provide a list of each separate location.

The THCSA program received 198 initial registrations and 236 renewals for a total of 434 registrations between July 1, 2023, and June 30, 2024. Forty-two of those applications were considered incomplete due to missing documentation. Required documentation includes documentation of professional liability or medical malpractice insurance not less than \$500,000 to insure against loss, damages, or expenses incident to a claim arising out of the death or injury of any individual as the result of negligence or malpractice in the provision of health care services by the THCSA or an employee, agent, or contractor of the THCSA; documentation of insurance coverage for workers' compensation for all health care personnel provided or procured by the THCSA; and documentation of a dishonesty bond for each THCSA employee in the amount of \$10,000. The THCSA program received a total of 8 complaints between July 1, 2023, and June 30, 2024.

## **Mother's Milk Banks**

Effective August 3, 2020, the Pennsylvania Department of Health was responsible for licensing Mothers' Milk Banks per the requirements of Act 7 of 2020.

Donor milk banks are a service that collect, screen, process, pasteurize and dispense by prescription human milk provided by nursing mothers who are not biologically related to the recipient infant. The largest group of recipients are premature babies, infants with gastrointestinal disorders, metabolic disorders or growth failure while on formula.

Donor milk banks that do business in Pennsylvania are licensed by the Department. Hospital-based milk banks that only use donor milk for its patients are exempt from the licensure requirement. As of June 30, 2024, there were 5 milk banks licensed in the Commonwealth. This is an increase of 3 (150%) from the last SFY.

**Table 7. Biennial Milk Bank Report 2023- 2024**

Milk Bank and Location	Donated Milk	Processed Milk	Milk Distributed in PA
Mid-Atlantic Mothers’ Milk Bank (Three Rivers) 3127 Penn Ave. Pittsburgh (Allegheny County), PA 15201	416,207 oz.	416,207 oz.	388,540 oz.
Prolacta Bioscience 1800 Highland Ave. Duarte (Los Angeles County), CA 91010	7,266,498 oz.	0 oz.	0 oz.
Prolacta Bioscience 757 N. Baldwin Park Blvd. City of Industry (Los Angeles County), CA 91746 <i>Processes and distributes milk donated at the Duarte location.</i>	0 oz.	7,343,594 oz.	27,667 oz.
Ohio Health Mothers’ Milk Bank 44850 E. Main St. Suite 140, Columbus (Franklin County), Ohio 43213	5,879 oz.	0 oz.	17,400 oz.
Mothers’ Milk Bank Northeast 377 Elliot St. Newton Upper Falls (Middlesex County), MA 02464	662,961 oz.	747,961 oz.	569,880 oz.

Source: Division of Home Health, Division Director, Biennial Milk Bank Report 2023-2024. Pennsylvania Department of Health.