Department of Health

Oversight of Food Service Establishments

Report 2017-S-62 | April 2019

OFFICE OF THE NEW YORK STATE COMPTROLLER
Thomas P. DiNapoli, State Comptroller

Division of State Government Accountability

Audit Highlights

Objective

To determine whether the Department of Health adequately monitors designated health departments' oversight of food service establishments to ensure they comply with the State Sanitary Code to prevent or mitigate outbreaks of foodborne illness. This audit covers the period January 1, 2014 through April 12, 2018.

About the Program

The Centers for Disease Control and Prevention (CDC) estimates that, each year, roughly 48 million people in the United States – or 1 in 6 Americans – get sick from a foodborne illness. Compliance with health codes and guidelines can help protect public health and prevent some of these illnesses.

The Department of Health (Department), through its Division of Environmental Health Protection, is responsible for overseeing New York State's more than 90,000 food service establishments (Establishments) and for ensuring that those Establishments are adhering to the State Sanitary Code (Code). The Department administers regulatory programs designed to minimize environmental health threats and provides policy directives and implementation guidance to county and city health departments and State regional and district offices. The Department's oversight is implemented at the local level through four regional offices (Capital, Central, Western, and Metropolitan) responsible for county and city health departments and the Department's district offices. Thirty-six counties and the City of New York have a health department; the 21 counties without full-service health departments rely on the Department's district offices. Hereafter, we collectively refer to the county and city health departments, including the New York City Department of Health and Mental Hygiene, and Department district offices as designated health departments. These departments are responsible for permitting and inspecting Establishments to ensure compliance with the Code and investigating complaints and reports of foodborne illness. They must also notify the Department when they initiate an investigation of a foodborne illness outbreak or when an unusual prevalence of foodborne illness is identified. Consumers may submit food-related complaints against Establishments to their designated health department. The Department requires each designated health department to investigate all complaints and reports of foodborne illness in an accurate, complete, and timely fashion. Designated health departments must maintain a surveillance system to record complaints and identify possible foodborne illness outbreaks.

Key Findings

- The Department has implemented inspection, complaint and outbreak investigation, and enforcement procedures and requirements for designated health departments to follow to ensure compliance with the Code to prevent or mitigate outbreaks of foodborne illness. However, designated health departments have not conducted inspections as frequently as recommended, and not all high-risk Establishments are inspected by more highly trained inspectors, as the Department recommends, hindering the Department's

oversight ability. Department reports show that high-risk Establishments were inspected twice a year, as recommended, only 44 percent of the time. Another report showed the percentage of high-risk Establishments inspected by more highly trained inspectors steadily decreased from 76 percent in 2014 to 64 percent in 2017.

- Designated health departments are not adequately ensuring enforcement of, or documenting justifications for the absence of, actions to address Category I public health hazards, as directed by the Department. Overall, of the 984 Category I violations, 717 (73 percent) resulted in no enforcement action, and for 590 of the 717 (82 percent), inspectors also did not provide justification for the lack of enforcement actions.
- We found systemic issues with the quality of data the Department relies on to carry out its oversight of Establishments. Error-prone reporting and problems transmitting data from designated health departments to the Department's Environmental Health Information and Permitting System (EHIPS) have resulted in data inaccuracies. Such deficiencies, along with inconsistent use of reporting functions, diminish the Department's ability to conduct useful analyses and to provide meaningful information to designated health departments – information that could help designated health departments focus their limited resources on areas of highest risk to consumers.

Key Recommendations

- Implement procedures to incorporate periodic data analysis and consistent use of EHIPS reporting mechanisms to:
  - Assess the performance of designated health department functions that need improvements;
  - Identify patterns and/or areas of concern involving non-compliance with the Code; and
  - Provide information to regional offices and designated health departments to assist them in the most effective allocation of staff resources (i.e., to more effectively assign certified inspectors and assess risk levels of Establishments).
- Ensure that designated health departments take enforcement action for Category I violations or document justification for not doing so, especially for Establishments that demonstrate a pattern of repeated violations.
- Take steps to improve the accuracy and completeness of EHIPS data including, but not necessarily limited to:
  - Implementing procedures for input, quality assurance, and utilization of information; and
  - Developing fixes for data errors and the inability to transmit data from designated health departments to EHIPS.

Office of the New York State Comptroller
Division of State Government Accountability

April 5, 2019

Howard A. Zucker, M.D., J.D.
Commissioner
Department of Health
Corning Tower
Albany, NY 12237

Dear Dr. Zucker:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage government resources efficiently and effectively. By so doing, it provides accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities, and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit entitled *Oversight of Food Service Establishments*. The audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

Division of State Government Accountability

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Glossary of Terms

Abbreviation	Description	Identifier
CDC	Centers for Disease Control and Prevention	*Federal Agency*
Code	New York State Sanitary Code	*Key Term*
Department	Department of Health	*Auditee*
Designated health departments	County and city health departments, including New York City Department of Health and Mental Hygiene, and Department district offices	*Key Term*
EHIPS	Environmental Health Information and Permitting System	*Key Term*
Establishments	Food service establishments	*Key Term*
FSIO	Food Service Inspection Officer	*Key Term*

Background

Foodborne illness is triggered by consuming contaminated food and beverages. Common contaminants include bacteria, viruses, and parasites. Symptoms may include nausea, vomiting, diarrhea, or fever, and onset of illness ranges from hours to days. Because symptoms can mimic the flu and appear long after the consumption of contaminated food, foodborne illnesses are not always reported or even correctly identified. While everyone is at some risk, the potential to become ill and the effects of those illnesses can be more serious for vulnerable populations such as infants, the elderly, pregnant women, and persons with compromised immune systems. Effects may not be limited to the initial symptoms, sometimes leading to chronic disease, permanent disability, or even death.

The Centers for Disease Control and Prevention (CDC) estimates that, each year, roughly 48 million people in the United States – or 1 in 6 Americans – get sick from a foodborne illness. Of those, 128,000 are hospitalized and 3,000 die. Compliance with health codes and guidelines can prevent some of these illnesses, possibly saving lives and protecting public health.

The Department of Health (Department), through its Division of Environmental Health Protection, is responsible for overseeing New York State's more than 90,000 food service establishments (Establishments) and for ensuring that those Establishments are adhering to the State Sanitary Code (Code). The Department administers regulatory programs designed to minimize environmental health threats, and provides policy directives and implementation guidance to county health departments and State regional and district offices. In addition to Establishments, the Division of Environmental Protection, among other responsibilities, oversees public beaches, swimming pools, and aquatic spraygrounds; hotels and motels; tanning facilities; tattoo facilities; and campgrounds and agricultural fairgrounds.

The Code requires Establishment owners and operators to run their facilities in a manner that avoids imminent health hazards (i.e., violations that make it probable that the Establishment's continued operation or the food and/or drink served could injure the health of the consumer or the public). The Department issues various procedural guidance documents to regional and district offices, as well as city and county health departments, to help ensure Establishments are operating in compliance with the Code.

The Department's oversight is implemented at the local level through four regional offices (Capital, Central, Western, and Metropolitan) responsible for county and city health departments and the Department's district offices. Thirty-six counties and the City of New York have their own full-service health departments; the remaining 21 counties are covered by the appropriate

Department district offices. County and city health departments, including the New York City Department of Health and Mental Hygiene and the Department's district offices (collectively referred to as designated health departments), are responsible for permitting and inspecting Establishments to ensure compliance with the Code.

Designated health departments are responsible for investigating complaints and reports of foodborne illnesses and must notify the Department when they initiate an investigation of a foodborne illness outbreak (i.e., a confirmed case of two or more people becoming ill from the same contaminated food) or when an unusual prevalence of foodborne illness is identified. The Department directs consumers to submit complaints to their designated health department and requires each health department to investigate all complaints and reports of foodborne illness in an accurate, complete, and timely fashion. Designated health departments must maintain a surveillance system to record complaints and identify possible foodborne illness outbreaks.

Not all Establishments present the same risk of causing foodborne illnesses, and the Department assesses risk level based on the nature of Establishments' menus and populations served. The Department groups Establishments into one of three risk levels: high, medium, or low risk, as shown in the following table.

Department Risk Levels by Establishment Type

Risk Level	Risk Factors	Establishment Type
High	Serve potentially hazardous foods with advanced preparation of complex food items involving cooling and reheating	• Restaurants (non-fast food) • Schools that prepare food • Diners
Medium	Serve potentially hazardous foods limited to cook-and-serve operations generally not including cooling and reheating	• Fast-food restaurants • Pizza parlors • Short-order establishments • Schools receiving prepared foods
Low	Serve very few potentially hazardous foods, and those served are generally prepackaged	• Bars • Taverns • Retail bakeries • Coffee shops

The Department establishes inspection frequencies based on risk level. High-risk Establishments should be inspected, on average, twice per year; medium-risk, once per year; and low-risk, once every two years. Additionally, the Department recommends that individuals inspecting high-risk Establishments receive advanced training and obtain a Food Service Inspection Officer (FSIO) Level 1 certificate, which indicates proficiency in uniform food service inspection techniques. Federal guidance outlined in the Food and Drug Administration's Food Code suggests the use of additional criteria – such as food establishments' history of violations and code compliance – for determining inspection frequency. However, the Department does not consider such factors in its risk assessment.

The Department categorizes Code violations as either critical or non-critical. Critical violations pose the greatest risk of health hazards to the public. Critical violations must be immediately corrected or the establishment must cease operations. Critical violations that pose the greatest risk to the public are categorized as Category I public health hazards and include issues with food from unapproved sources, adulterated or contaminated food, potentially hazardous foods stored out of appropriate temperature ranges, exposure to foods by ill persons, sewage concerns, and inadequate drinkable water supplies.

Designated health departments must take action against Establishments for all Category I public health hazards and, to the extent formal enforcement action is not initiated, they should document their justifications for not doing so. Lesser hazards require no enforcement actions. Formal enforcement measures may include administrative hearings, formal stipulations, fines, court actions, and/or closures.

The Department monitors Establishments throughout the State through its Environmental Health Information and Permitting System (EHIPS). EHIPS serves as a central repository for inspection data – including violations – for designated health departments. The Department allows municipalities to use different systems to capture inspection data; however, the systems must be capable of loading the information into EHIPS. Suffolk, Erie, and Westchester counties and New York City utilize their own information systems and upload their data into EHIPS quarterly.

The Department reported that, between January 1, 2014 and September 18, 2017, designated health departments completed over 417,000 inspections representing 96,761 establishments. These inspections resulted in more than 1.2 million violations of the Code, including over 200,000 critical violations (16.7 percent) and over 38,000 imminent health hazards (3.2 percent).

Audit Findings and Recommendations

The Department has implemented inspection, complaint and outbreak investigation, and enforcement procedures and requirements for designated health departments to follow to ensure compliance with the Code and to prevent or mitigate outbreaks of foodborne illness. However, designated health departments have not been able to conduct inspections as frequently as recommended, hindering the Department's oversight ability. Additionally, not all high-risk Establishments are inspected by FSIO Level 1 certified inspectors, as the Department recommends.

Designated health departments are also not adequately ensuring enforcement of, or documenting justifications for the absence of, actions to address Category I public health hazards. We reviewed 984 Category I violations cited in calendar years 2016 and 2017 at ten designated health departments to determine whether the designated health departments were taking formal enforcement actions. Overall, 717 Category I violations (73 percent) resulted in no enforcement action. The designated health departments could not provide documented justifications for lack of enforcement actions for 590 of the 717 violations (82 percent).

Additionally, we found systemic issues with the quality of data the Department relies on to carry out its oversight of Establishments. Error-prone reporting and problems transmitting data from designated health departments to EHIPS have resulted in data inaccuracies that render the data unreliable, hindering the Department's ability to monitor designated health departments' inspection activities and ensure Code compliance. Additionally, regional offices inconsistently utilize the reporting functions within EHIPS, further limiting its usefulness as a monitoring tool.

Because not all designated health departments complete all inspections recommended by the Department (with many attributing their shortfalls to a lack of resources, particularly staffing), effective data analysis could help them target their limited resources to areas of greatest need or at highest risk. Robust data and systems are key tools for constructively analyzing risks, and their effective use could enable the Department to more accurately identify performance strengths and weaknesses within designated health departments.

We found that designated health departments have effective systems for both responding to foodborne illness outbreaks and for protecting the public from further contamination. However, a lack of guidance from the Department has created inconsistencies in complaint investigations across designated health departments.

Inspections and Enforcement

Inspections

Designated health departments have not been able to conduct inspections as frequently as recommended, and not all high-risk Establishments are inspected by FSIO Level 1 certified inspectors as the Department recommends, hindering the Department's oversight ability. Despite limitations in the data, the Department provided a report about the frequency of inspections at high-risk Establishments (excluding Suffolk County and New York City) for calendar years 2014 through 2017. This report showed high-risk Establishments were inspected twice a year, as recommended, only 44 percent of the time. Another report showed the percentage of high-risk Establishments inspected by FSIO Level 1 certified inspectors steadily decreased from 76 percent in 2014 to 64 percent in 2017.

Designated health departments largely attributed their inspection shortfalls to a lack of resources, such as staffing (e.g., staff vacancies). Additionally, officials stated competing program responsibilities and fluctuations in activity – such as increased inspections of children's camps during summer months – have also contributed to performance shortfalls. Similarly, regional office staff have expressed that staffing shortfalls limit their ability to adequately monitor and assist designated health departments. In some regional offices, the Department has few regional field coordinators (who work directly with designated health departments) to observe and assess compliance with State standards. For example, the Metropolitan Region (which accounts for about 75 percent of the Establishments statewide) has only one field coordinator to cover New York City and the ten surrounding counties, including all of Long Island.

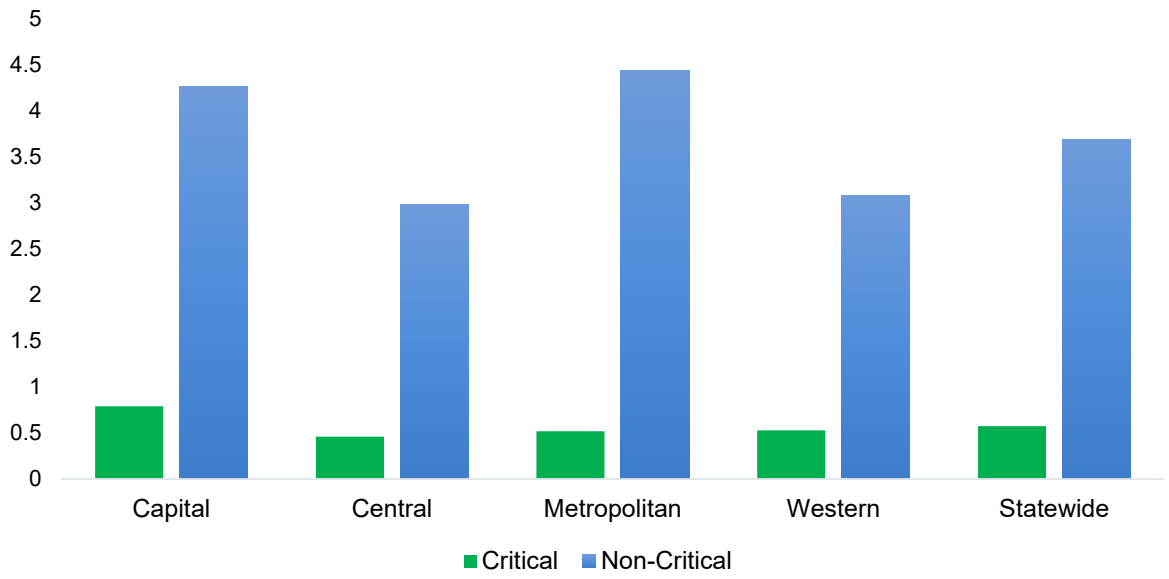
Improved data and analytics of inspection activity could help the Department identify patterns and trends – such as Establishments that could be inspected less frequently without significant risk, additional patterns of problems, or red flags – which could aid in assessing risks related to inspection activities. The results of such analyses, in conjunction with guidance from the Department, could help designated health departments allocate their limited resources to the areas that pose the highest risk to consumers, ultimately improving assurances that Establishments are operating in compliance with the Code.

Although Department officials stated they do review some EHIPS data, we found their analyses are quite broad and are of limited use to the regional offices responsible for direct oversight of the designated health departments. Routine and targeted analyses that specifically meet the needs of individual designated health departments could be more useful.

Department officials stated that EHIPS information indicates the number of FSIO Level 1 certified inspectors has been decreasing, consequently reducing the inspection rate of high-risk Establishments by certified inspectors. In response, the Department revised the process for FSIO Level 1 certification, streamlining and clarifying defined time frames for completion of fieldwork training. Additionally, in 2015, the Department took steps to further meet inspection guidelines for high-risk Establishments. Such efforts included adding summer staff to assist with the workload and providing cell phones and tablets to inspectors to increase inspection efficiency and improve communication.

According to the 2017 report on critical violation rates, the statewide average for critical violations per inspection was 0.55, and for non-critical violations, 3.85 (see the following graph). The Capital Region identified the highest rate of critical violations (0.79 per inspection), the Central Region had the lowest critical violations rate of 0.46 per inspection, and the Metropolitan Region had the highest non-critical violations rate of 4.44 per inspection.

Per-Inspection Violation Rates (Critical vs. Non-Critical) per Region in 2017



While this data is available to the Department, it is not being used to evaluate risk when planning future inspections. Given the risk posed by critical violations to public health, the Department should consider factoring the number of these violations cited at Establishments into its risk assessment for determining the frequency of inspections. Establishments that frequently have higher rates of critical violations, regardless of the food they serve or

how it is prepared, may demand more attention than those designated high risk using the current model. Adding the number of past critical violations or related factors (such as Establishments' responses to past violations) to the Department's considerations for assessing Establishment risk level could result in more effective use of limited inspection resources.

We observed 90 inspections among five district offices covering six designated health departments, including New York City. For those 90 inspections, inspectors cited 1,126 violations, of which 243 (21.6 percent) were critical. Generally, we observed inconsistencies in how inspections were conducted, indicating additional guidance may be necessary to ensure consistency in how inspections are conducted. We found some inspectors focused on general sanitary conditions rather than conducting a more risk-based inspection. For example, some inspectors focused on conditions that would more likely affect the health and safety of consumers, such as dirty cutlery or equipment, while other inspectors focused on sink or bathroom areas. We also observed some violations that were missed by inspectors such as food being stored at the incorrect temperature, produce placed directly on the floor, and possible cross-contamination issues. Department officials responded that they train inspectors to focus on critical violations and the missed violations were non-critical. Additionally, they said the presence of more persons allowed for a greater ability to observe these violations. Officials stated that when multiple inspectors co-inspect an Establishment during training or job shadowing, similarly, more violations are noted.

Enforcement

Designated health departments are not adequately ensuring enforcement of, or documenting justifications for the absence of, actions to address Category I public health hazards. To determine whether the designated health departments were taking formal enforcement actions, we reviewed 984 Category I violations cited in calendar years 2016 and 2017 at ten designated health departments. Overall, 717 Category I violations (73 percent) resulted in no enforcement action, and for 590 of the 717 (82 percent), inspectors also did not provide justification for the lack of enforcement actions. In response to our preliminary findings, designated health departments provided additional information about these violations, stating that some were incorrectly identified as Category I in EHIPS due to inspector errors in citing the violations. Designated health departments also stated that they took action for some of these violations, but did not provide us with more specific information about these actions.

The Department also cannot easily monitor enforcement activities or determine if inspectors provide adequate justification for not taking actions

to address violations. This information is maintained only by the designated health departments, and the Department does not require that it be loaded into EHIPS. Nonetheless, over half of the designated health departments include this information in EHIPS, with others using their own in-house systems.

Inspectors expressed confidence that other program initiatives – such as education – can help achieve Code compliance. Establishments with patterns of non-compliance may require stronger consequences, such as fines or other enforcement activities, coupled with education to deter poor practices and ensure greater Code compliance. However, if the Department does not capture this information in EHIPS, it cannot readily identify Establishments with patterns of non-compliance for which stronger enforcement might be more effective.

System Data Reliability and Use of Information in Reporting

EHIPS, the Department's primary system for monitoring designated health department activity (including inspections and violations issued to Establishments), is critical for ensuring Code compliance. We reviewed information in EHIPS and found inaccurate and/or incomplete data. While some errors originated from designated health departments' reporting issues, we traced others to flaws in how data is transmitted to EHIPS, data entry errors, and designated health departments' inconsistent recording of violations.

Additionally, there is limited verification of the data entered into EHIPS. Some verification should occur (e.g., a review of a small sample of inspection reports) during program reviews; however, these assessments are not routinely completed and there is no standard for how often they should be performed. The Department also does not have written standards for quality control or procedures for data utilization for EHIPS. Consequently, there is no assurance that the data in EHIPS is accurate or complete, making it unreliable for purposes of analysis and informed decision making. Further, while the Department has developed report functionalities within EHIPS to provide oversight of designated health departments, the Department does not consistently use these functions. EHIPS' usefulness as a monitoring tool is diminished by its inconsistent application.

Data Reliability

We reviewed EHIPS inspection data for the period January 1, 2014 through

September 18, 2017 and found it was incomplete and contained errors. Typical errors included duplication of inspections and violations, incorrectly cited violations, and miscategorized Establishment risk levels. Other issues included 13 months of missing data for Suffolk County and aggregated information resulting in transmission gaps and insufficient detail.

Further, due to inconsistencies among the Code and designated health departments' county codes, we found miscategorized critical and non-critical violations. For instance, Suffolk's county code is more stringent than the Code. Inspectors do not always differentiate between critical and non-critical Code violations because the county code does not differentiate. For example, inspectors issued the same citation for observed, actual bare-hand contact and the mere potential for bare-hand contact. Actual bare-hand contact is a critical Code violation, whereas the potential for bare-hand contact is non-critical. Ensuring accurate recording of violations – especially critical violations – is important, as that information indicates problems in an Establishment's operating processes that may pose a risk to public health.

Department officials believe that many of these issues have no substantive effect on their ability to use the data. Department staff use EHIPS data on a statewide level to evaluate trends in inspection performance, staff training, and violations identified and to guide the development of regulations, guidance, and training programs. Department staff told us that, when necessary, they can work with designated health departments to obtain missing data to complete their analysis. The Department also works directly with designated health departments to observe and assess compliance standards. Despite this established collaboration, prior to the engagement of our audit, the Department had not requested the missing months of Suffolk County information, nor had Department staff or designated health departments identified or corrected any of the data inaccuracies. Department officials stated they became aware of Suffolk County's issue with uploading data in the summer of 2017, and they believe it occurred due to a lack of resources. The Department continues to work with Suffolk County to resolve the issue. Nonetheless, as the EHIPS data remains incomplete and inaccurate, the usefulness of analysis the Department may have performed to ensure Establishments' and designated health departments' Code compliance is diminished.

Use of EHIPS Data in Reporting

The Department has developed the framework, including report functionalities within EHIPS, to monitor designated health departments' oversight of Establishments' compliance with the Code. While there is a user manual that identifies reporting tools designated health departments may utilize, there

are no written procedures or guidance on how regional offices or designated health departments should be using information in EHIPS to monitor Code compliance. Consequently, regional offices are not consistently using these functions or the EHIPS data. Reporting information on issues such as agency goals and employee concerns to management helps promote accountability for actions and decisions, but only when it is consistent, timely, and relevant to its users. The inconsistent use of the available reporting functions diminishes EHIPS' usefulness as a management tool to obtain current, meaningful information on designated health departments to monitor program compliance.

EHIPS is capable of producing reports that can assist the Department in monitoring designated health departments' oversight of Establishments' compliance with the Code and indicate where additional technical assistance or training is needed. For example, Department officials can run reports to determine if high-risk Establishments have been inspected by FSIO-certified inspectors or to determine inspection backlogs. Although EHIPS has the functionality to generate reports on inspection data (including on a statewide basis), which can be used by regional offices to complete comprehensive reviews of designated health departments to monitor performance and compliance with the Code, this is not generally done.

For calendar years 2014 through 2017, the Capital Region (the regional office that most heavily used EHIPS' reporting capabilities) conducted 23 program reviews using EHIPS' reporting capabilities to analyze various aspects of performance, including total inspections, number of second inspections for high-risk Establishments, complaints received and resolved, and number of outbreaks. The Metropolitan Region conducted only two such reviews, and the Central and Western Regions conducted none. The Western Region, however, did use certain types of reports on an as-needed basis (e.g., number of Establishments inspected by FSIO-certified inspectors).

Investigations of Outbreaks and Complaints

Based on our review of a sample of outbreaks at eight designated health departments, we found that they had effective systems in place to respond to the foodborne illness outbreaks and protect the public from further contamination. However, a lack of guidance from the Department has created inconsistencies in complaint investigations across the designated health departments.

The Department has developed policies and procedures for designated health departments and regional offices for investigating foodborne illness outbreaks. These procedures outline inspectors' responsibilities and help

them to consistently identify the pertinent information they should record. We reviewed the actions taken for 39 of 85 outbreaks at eight designated health departments and found the outbreaks were effectively investigated to determine the source of the outbreak, prevent further contamination, and educate operators to prevent future outbreaks. Additionally, the Department provided statewide training to designated health departments on how to investigate and respond to illness complaints based on standards set forth by the Council to Improve Foodborne Outbreak Response (a multidisciplinary collaboration of national associations and federal agencies – co-chaired by the Council of State and Territorial Epidemiologists and the National Association of County and City Health Officials – that works to detect, investigate, control, and prevent foodborne disease outbreaks). New York City also undertook a pilot program to analyze social media sites to identify possible complaints involving foodborne illnesses.

The Department, however, does not provide similarly detailed procedures for investigating complaints to designated health departments. Specifically, it does not define what constitutes an accurate, complete, and timely investigation. As such, we found designated health departments implement widely varying complaint investigation processes. Although specific complaint circumstances might dictate how a designated health department proceeds, a general framework could lead to more consistent investigations and record keeping. This consistency would assist with the Department's review of the timeliness, type, and severity of complaints statewide, possibly identifying best practices or areas of improvement in complaint investigations.

We reviewed a sample of 567 complaints between 2016 and 2017 for ten designated health departments and found that each had surveillance systems in place, but each also had different methods to investigate complaints. For example, some designated health departments use their epidemiology departments to prioritize complaints before initiating inspections. Based on information such as incubation periods (the time between the consumption of food and illness symptoms), the epidemiology departments may determine that some complaints do not warrant investigation. Other designated health departments do not have or might not utilize their epidemiology departments, conducting inspections for all complaints instead. Department officials stated they are developing a new complaint system, which they will require designated health departments to use. The new system should assist the Department in analyzing complaint and outbreak information.

Recommendations

1. Implement procedures to incorporate periodic data analysis and consistent use of EHIPS reporting mechanisms to:
   - Assess the performance of designated health department functions that need improvements;
   - Identify patterns and/or areas of concern involving non-compliance with the Code; and
   - Provide information to regional offices and designated health departments to assist them in the most effective allocation of staff resources (i.e., to more effectively assign FSIO-certified inspectors and assess risk levels of Establishments).
2. Ensure that designated health departments take enforcement action for Category I violations, or document justification for not doing so, especially for Establishments that demonstrate a pattern of repeated violations.
3. Take steps to improve the accuracy and completeness of EHIPS data including, but not necessarily limited to:
   - Implementing procedures for input, quality assurance, and utilization of information; and
   - Developing fixes for data errors and the inability to transmit data from designated health departments to EHIPS.
4. Develop procedures that provide a basic framework for complaint investigations to improve consistency and standardize the information recorded for investigations.

Audit Scope, Objective, and Methodology

The objective of our audit was to determine whether the Department adequately monitors designated health departments' oversight of Establishments' compliance with the Code to prevent or mitigate outbreaks of foodborne illness. This audit covers the period January 1, 2014 through April 12, 2018.

To achieve our audit objective, we interviewed officials from the Department and designated health departments. We reviewed and gained an understanding of the Code and Department policies and procedures. We became familiar with, and assessed the adequacy of, internal controls related to the Department's monitoring of designated health departments' oversight of Establishments' compliance with the Code.

We obtained and analyzed inspection data from EHIPS for the period January 1, 2014 to September 18, 2017 to determine the reliability and accuracy of the data. We found instances of inaccurate or incomplete information in EHIPS. Therefore, we deemed the data to be unreliable and limited our reliance on the data to support our audit findings, using hard copy records wherever possible and qualifying the reliability of the data in the report when it was used. We judgmentally selected designated health departments to assess the Department's oversight and the reliability of the EHIPS inspection data. Overall, we selected 13 designated health departments, including 7 counties, 5 district offices, and New York City. We selected larger designated health departments with at least one district office in each of the Department's four regions. We also selected designated health departments based on certain risk factors, including those with their own information systems and low rates of critical violations. For each designated health department, we attended inspections of high-risk Establishments to observe inspection methods and identification and proper citation of violations. We selected inspectors based on the designated health departments' schedule of upcoming inspections and inspector availability. In total, we observed 90 inspections (51 conducted by city or county health departments and 39 conducted by district offices) conducted by 36 inspectors.

We sampled foodborne illness complaints for 2016 and 2017 for each of 10 of the 13 designated health departments, including six counties (Erie, Nassau, Onondaga, Schenectady, Suffolk, and Westchester), three district offices (Geneva, Monticello, and Watertown), and New York City to compare complaint surveillance systems across departments. We excluded general complaints, such as those related to sanitary conditions, to align with our audit objective. For five designated health departments, we selected all illness complaints for 2016 and 2017 because there were fewer than 45 complaints each year. For the other five designated health departments, we selected

a random sample of illness complaints. In total, we reviewed 567 out of 7,564 illness complaints. Although we selected random samples in certain instances, our conclusions cannot be projected to the population of illness complaints as a whole.

For the same ten designated health departments, we reviewed outbreaks to assess the effectiveness of investigations and actions taken to mitigate the public's exposure to health risks. We reviewed either all the outbreak investigations from each designated health department completed during the scope period (due to the designated health department having only a limited number of investigations), or selected some from the 2016 and 2017 calendar years (for designated health departments with more investigations). For Onondaga and Schenectady counties, we selected all outbreak investigations completed during our audit scope (five and two, respectively). For New York City, we randomly selected 2 of 23 outbreak investigations in 2016 and 2 of 20 outbreak investigations in 2017. For Nassau County, we randomly selected two of six outbreak investigations in 2016 and the two outbreak investigations completed in 2017. For Westchester County, we selected the only outbreak investigation from 2016 and randomly selected three of six outbreak investigations completed in 2017. For Suffolk County, we selected all outbreak investigations in 2016 and 2017 (eight and two, respectively). For Erie County, we selected all outbreak investigations in 2016 and 2017 (two and one, respectively). For the Geneva district office, we selected all outbreak investigations in 2016 (two). Geneva did not complete any outbreak investigations in 2017. The Watertown and Monticello district offices did not complete any outbreak investigations during the audit scope period. In total, we reviewed 39 of 85 outbreak investigations. Although we selected random samples in certain instances, our conclusions cannot be projected to the population of outbreak investigations as a whole.

Using EHIPS, we identified Category I violations and reviewed enforcement actions and compliance with State standards at the same ten designated health departments. We reviewed all the identified Category I violations for six designated health departments and selected random samples at the other four designated health departments. In total, we reviewed 984 of 18,824 Category I violations. Although we selected random samples in certain instances, our conclusions cannot be projected to the population Category I violations as a whole.

Statutory Requirements

Authority

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members to certain boards, commissions, and public authorities, some of whom have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

This audit was performed pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

Reporting Requirements

We provided a draft copy of this report to Department officials for their review and formal comment. We considered their comments in preparing this final report and attached them in their entirety at the end. In general, officials agree with our recommendations, but took exception to our reflection of how the Department uses its data analysis in both routine assessment of performance and ad hoc analysis to address specific concerns.

Within 90 days of the final release of this report, as required by Section 170 of the Executive Law, the Commissioner of Health shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, advising what steps were taken to implement the recommendations contained herein, and where recommendations were not implemented, the reasons why.

Agency Comments

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

March 29, 2019

Mr. Stephen Goss, Audit Director
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, New York 12236-0001

Dear Mr. Goss:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2017-S-62 entitled, "DOH Oversight of Food Service Establishments."

Thank you for the opportunity to comment.

Sincerely,

Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

Enclosure

cc: Marybeth Hefner
Diane Christensen
Jeffrey Hammond
Jill Montag
Brad Hutton
Gary Ginsberg
Michael Cambridge
Brian Miner
Ryan Cox
Jessica Lynch
Lori Conway

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Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2017-S-62 entitled,
"DOH Oversight of Food Service Establishments"

The following are the Department of Health's (Department) comments in response to the Office of the State Comptroller's (OSC) Draft Audit Report 2017-S-62 entitled, "DOH Oversight of Food Service Establishments" (the Report).

Recommendation #1

Implement procedures to incorporate periodic data analysis and consistent use of EHIPS reporting mechanisms to:

- Assess the performance of designated health department functions that need improvements;
- Identify patterns and/or areas of concern involving non-compliance with the Code; and
- Provide information to regional offices and designated health departments to assist them in the most effective allocation of staff resources (i.e., to more effectively assign FSIO-certified inspectors and assess risk levels of Establishments).

Response #1

The Report does not reflect a comprehensive understanding of the many ways that the Department uses data analysis for both routine assessment of performance measures and ad hoc analysis to address specific concerns. However, the Department agrees with the recommendation to more routinely assess Local Health Department (LHD) performance. The Department has updated the formal, annual review of LHD programs by Regional Office staff using a uniform survey tool. Regional Office staff will conduct assessments of LHDs throughout 2019 and the program review tool will be used to evaluate LHD performance across many aspects of the food protection program including: establishment permitting, frequency of inspection of establishments, percentage of high-risk inspections performed by a certified Food Service Inspection Officer, identification and correction of public health hazards, enforcement, and foodborne illness complaint investigation. The Department will also review its guidance on Regional Office oversight of LHD programs and revise as necessary to ensure that it is current and consistent with Department expectations.

LHDs must prioritize the various inspection activities that fall within the scope of their responsibilities. The Report suggests that establishments' history of compliance should be considered when determining the appropriate inspection frequency and recommends that EHIPS reporting mechanisms be used to ensure effective allocation of staff resources. The Department agrees and is confident that this is already occurring. EHIPS already contains various report functions which allow LHDs to use permit and inspection data to effectively implement their food protection program. These reports were developed with significant input from LHDs to address their data needs. The Department will consider additional information reporting needs of the LHDs and the Regions as it works to further improve EHIPS functionality. The Department will also consider incorporating compliance-based prioritization into inspection frequency guidance.

Recommendation #2

Ensure that designated health departments take enforcement action for Category I violations, or document justification for not doing so, especially for Establishments that demonstrate a pattern of repeated violations.

Response #2

The Department agrees with the recommendation and acknowledges that LHDs are not always either taking enforcement action for Category 1 Public Health Hazards or documenting reasons for not doing so. Often the Public Health Hazards are corrected or mitigated at the time of inspection. The absence of later enforcement does not further jeopardize public health when LHDs utilize other methods to educate operators and ensure future compliance. The Department will review its guidance on enforcement, provide clarification as necessary, and monitor LHD enforcement actions as part of program reviews by Regional staff as discussed in Recommendation #1.

Recommendation #3

Take steps to improve the accuracy and completeness of EHIPS data including, but not necessarily limited to:

- Implementing procedures for input, quality assurance, and utilization of information; and
- Developing fixes for data errors and the inability to transmit data from designated health departments to EHIPS.

Response #3

The Report identifies certain inaccuracies and inconsistencies in inspection data entered or transferred into the Department's Environmental Health Information and Permitting System (EHIPS), including issues with Suffolk County not effectively providing inspection data to the Department. Suffolk County has since resolved the issues associated with data transfer and the missing data is now available. The Department will continue to monitor and ensure timely transmission of facility and inspection data by all counties using data transfer methods.

Data transfer issues aside, the number of inaccuracies identified were relatively few and do not significantly impact the Department's ability to evaluate statewide trends. However, the Department agrees that it is important to minimize data inaccuracies. One major initiative seeking to improve data quality that the Department is undertaking, is the implementation of electronic inspection forms, which reduces data entry steps necessary to import data to EHIPS. The Department is committed to expanding the use of electronic inspection reports throughout its programs and encouraging their use across all LHDs.

Recommendation #4

Develop procedures that provide a basic framework for complaint investigations to improve consistency and standardize the information recorded for investigations.

Response #4

The Department does not differentiate between foodborne illness complaint and outbreak investigations. Standard procedures and guidance for investigation of illness complaints are provided to LHDs as part of the Department's outbreak investigation guidance since many foodborne outbreaks are identified through the investigation of foodborne illness complaints. Each LHD is required to develop and maintain a surveillance system to record complaints and identify possible foodborne disease incidents/outbreaks, verify the incident/outbreak and notify the Department Regional Office if an outbreak is identified. More prescriptive standardization of complaint/outbreak investigation procedures is impractical because LHDs differ in their organizational structure and available resources.

As noted in the Report, the Department is developing a statewide complaint system which will provide a central reporting mechanism to be accessed and monitored by both environmental health and communicable disease staff at the local and state level. The Department is also revising its outbreak investigation guidance to include more robust technical reference material in addition to the existing procedural guidance.

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