Department of Health

Use, Collection, and Reporting of Infection Control Data

Report 2020-S-55 | March 2022

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 (Department) is collecting necessary data to make informed decisions and promote strong infection prevention and control policies, and whether the data collected by the Department, including data reported to the public, is accurate and reliable. The audit covered the period from January 2017 through November 2021.

About the Program

On February 28, 2020, a case of coronavirus disease 2019 (COVID-19) was identified in a resident of a long-term care skilled nursing facility in King County, Washington. The patient died on March 2. In the aftermath, 81 residents, 34 staff members, and 14 visitors would ultimately test positive, and at least 37 people would die.[1] A March 18, 2020 report on this outbreak published by the Centers for Disease Control and Prevention (CDC) concluded:

> Once COVID-19 has been introduced into a long-term care facility, it has the potential to result in high attack rates among residents, staff members, and visitors. In the context of rapidly escalating COVID-19 outbreaks in much of the United States, it is critical that long-term care facilities implement active measures to prevent introduction of COVID-19. … Substantial morbidity and mortality might be averted if all long-term care facilities take steps now to prevent exposure of their residents to COVID-19. The underlying health conditions and advanced age of many long-term care facility residents and the shared location of patients in one facility places these persons at risk for severe morbidity and death. Rapid and sustained public health interventions focusing on surveillance, infection control, and mitigation efforts are resource-intensive but are critical to curtailing COVID-19 transmission and decreasing the impact on vulnerable populations, such as residents of long-term care facilities, and the community at large.[2]

Infection control is an essential component of any health care delivery. Infection control measures can be as simple as thorough handwashing and as sophisticated as high-level disinfection of surgical instruments or the use of personal protective equipment. Implementing these measures can prevent transmission of disease in health care settings and the community. Infection control is a key concept in achieving the Department's mission to protect and promote the health of New Yorkers through prevention, science, and the assurance of quality health care delivery. Although infection control practices were always essential, the COVID-19 pandemic elevated the importance of establishing and adhering to strong practices. Older people are at a disproportionately greater risk of developing severe and life-threatening symptoms due to physiological changes that come with aging and potential underlying health conditions. Due to the highly contagious nature of COVID-19, the pandemic has had devastating consequences for older populations residing in congregate settings, such as nursing homes. The Department is responsible for overseeing health care facilities (nursing homes, hospitals, and long-term care facilities – hereafter collectively referred to as facilities), and ensuring they comply with federal and State regulations.

1 U.S. Department of Health and Human Services, Office of Inspector General: Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23–May 30, 2020

2 McMichael TM, Clark S, Pogosjan S, et al.: COVID-19 in a Long-Term Care Facility – King County, Washington, February 27–March 9, 2020. *MMWR Morb Mortal Wkly Rep* 69:339–342

Under State regulations, facilities are required to establish and maintain an infection control program, with written policies and procedures designed to provide a safe, sanitary, and comfortable environment and help prevent the development and transmission of disease and infection.

The Department uses three systems for collecting and reporting infection control data: the Nosocomial Outbreak Reporting Application (NORA); Health Electronic Response Data System (HERDS); and nursing home surveys. Most health care-associated infection outbreaks are reported to the Department via NORA, which receives over 1,000 reports from facilities per year. The Department uses HERDS to collect data from facilities via surveys, which are specific to an issue or public health emergency on a given day. The COVID-19 pandemic-related HERDS survey is the only one the Department has continuously issued daily since March 9, 2020 and was still issuing as of November 18, 2021. HERDS surveys are also used to collect information on COVID-19 nursing home deaths. The Department also collects data through various surveys (e.g., quality of care, fire/safety, complaints, and most recently infection control).

Key Findings

- Providing access to government data engenders transparency and promotes public trust. While the Department's duty is to act solely to promote public health, we determined that, instead of providing accurate and reliable information during a public health emergency, the Department conformed its presentation to the Executive's[3] narrative, often presenting data in a manner that misled the public.
- The Department, as a result, was not transparent in its reporting of COVID-19 deaths at nursing homes. Whether due to the poor-quality data that it was collecting initially or, later, a deliberate decision, for certain periods during the pandemic, the Department understated the number of deaths at nursing homes by as much as 50%.
    - From April 12, 2020 to February 3, 2021, the Department frequently changed its basis for the public reporting of COVID-19 deaths in nursing homes (e.g., reporting only resident deaths that occurred at the nursing home vs. reporting all deaths regardless of where they occurred, such as at a hospital), with virtually no explanation publicly as to why it changed.
    - All told, for the nearly 10-month period from April 2020 to February 2021, the Department failed to account for approximately 4,100 lives lost due to COVID-19.
- Persistent underinvestment in public health over the last decade may have limited the Department's ability to prepare and respond in the most effective way. Department staff, by all accounts, worked tirelessly throughout the pandemic. However, better data and information systems and an established system of proactive infection control reviews for facilities prior to the pandemic would have provided them with more accurate and complete information early on to assist them in their work and would have helped facilities be better prepared. Moreover, once the pandemic began, rapid and sustained public health interventions, including surveillance, infection control, and mitigation efforts, were critical to curtailing COVID-19 transmission to decrease the impact on vulnerable populations, such as residents of nursing home facilities, and the community

3 The Executive is defined to mean the former Governor, the members of his staff within the Executive Chamber, and the members of the New York State Interagency Task Force, including former health commissioner Howard Zucker.

at large. However, such efforts are resource-intensive, and it is clear that the Department was not adequately equipped in this regard.

- Especially given staffing limitations, it is incumbent on the Department to maximize the effective use of all its other available resources, including data. However, the Department does not cooperatively use the various data sources at its disposal to promote strong infection control practices through policy recommendations and oversight in response to this – or any other – infectious disease event. The Department collects a substantial amount of different but related data from NORA, HERDS, and its nursing home surveys – data that, analyzed collectively, can provide far more valuable information than merely the sum of their parts. However, the Department does not routinely analyze the data broadly to detect interfacility outbreaks, geographic trends, and emerging infectious diseases or to shape its infection control practices and policies and its oversight of facilities.
- We experienced delays during the audit, with requests for information languishing at times for months. Further, Department officials frequently would not answer our questions posed during scheduled meetings, and instead asked us to submit our questions in writing afterward, to be answered at a later date.

Key Recommendations

To the Department:

- Develop and implement policies, procedures, or processes to:
  - Expand use of infection control data, including but not limited to NORA, HERDS, and nursing home survey data, to identify patterns, trends, areas of concerns, or non-compliance, and use this information as the basis for policy recommendations for infection control practices and for executing nursing home surveys, as necessary;
  - Improve quality of publicly reported data;
  - Strengthen communication and coordination with localities on collection, reporting, and use of infection control-related data; and
  - Collect supplemental data through additional sources, such as the CDC's Infection Control Assessment and Response tool, and incorporate its use with current data sets.
- Evaluate and request resources as necessary to establish a foundation to adequately address public health emergencies in furtherance of the Department's mission.

To the Governor:

- Assess and document the adequacy of the internal control environment at the Department and Executive Chamber, and take necessary steps to ensure the control environment is adequate, including cooperation with authorized State oversight inquiries, communication with localities, and external reporting.

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

March 15, 2022

Mary T. Bassett, M.D., M.P.H.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

Dear Dr. Bassett:

The Office of the State Comptroller is committed to helping State agencies, public authorities, and local government agencies manage their resources efficiently and effectively. By so doing, it provides accountability for the 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 *Use, Collection, and Reporting of Infection Control Data*. This audit was performed pursuant to the State Comptroller's authority under 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

Term	Description	Identifier
CDC	Centers for Disease Control and Prevention	*Federal Agency*
CMS	Centers for Medicaid & Medicare Services	*Federal Agency*
COVID-19	Coronavirus disease 2019	*Key Term*
Department	Department of Health	*Auditee*
Division	Division of Nursing Homes and Intermediate Care Facilities for Individuals with Intellectual Disabilities Surveillance	*Division*
Facilities	Nursing homes, long-term care facilities, and hospitals	*Key Term*
HERDS	Health Electronic Response Data System	*System*
ICAR	CDC's Infection Control Assessment and Response tool	*Key Term*
Infection Control surveys	Focused Infection Control surveys, required by CMS in response to the pandemic	*Key Term*
MARO	Metropolitan Area Region Offices	*Key Term*
NORA	Nosocomial Outbreak Reporting Application	*System*
PPE	Personal protective equipment	*Key Term*
SOM	State Operations Manual	*Law*
Standard Health surveys	Standard Health (quality of care) and Life Safety Code (fire and safety) surveys	*Key Term*
Task Force	New York State Interagency Task Force	*Key Term*

Background

Infection control is an essential component of any health care delivery. Infection control measures can be as simple as thorough handwashing and as sophisticated as high-level disinfection of surgical instruments or the use of personal protective equipment (PPE). Implementing these measures can prevent transmission of disease in health care settings and the community. Infection control is a key concept in achieving the Department of Health's (Department) mission to protect and promote the health of New Yorkers through prevention, science, and the assurance of quality health care delivery. Although infection control practices were always essential, the coronavirus disease 2019 (COVID-19) pandemic elevated the importance of establishing and adhering to strong practices.

While people of all ages are susceptible to contracting the disease, older people are at a disproportionately greater risk of developing severe and life-threatening symptoms due to physiological changes that come with aging and potential underlying health conditions. Due to the highly contagious nature of COVID-19, the pandemic has had devastating consequences for older populations residing in congregate settings, such as nursing homes.

The first case of COVID-19 in the United States – in Washington State – was confirmed on January 21, 2020. The first case in New York State was confirmed on March 1, 2020. Just 10 days later, the World Health Organization declared COVID-19 a pandemic. Since then, more than 50 million people in the United States have contracted the disease, and as of December 21, 2021, nearly 804,000 have died,[4] including over 47,000 New Yorkers.[5]

On February 28, 2020, a case of COVID-19 was identified in a resident of a long-term care skilled nursing facility in King County, Washington. The patient died on March 2 – just 3 days later. The local health department and the Centers for Disease Control and Prevention (CDC) took immediate action to investigate the growing cluster of respiratory illness in the facility, collecting information on symptoms, severity, comorbidities, travel history, and close contacts to known COVID-19 cases. Within one week, a total of 129 COVID-19 cases were confirmed among facility residents (81 of 130), staff members (34), and visitors (14); and ultimately at least 37 people would die.[6] A March 18, 2020 report on this outbreak published by the Centers for Disease Control and Prevention (CDC) concluded:

> Once COVID-19 has been introduced into a long-term care facility, it has the potential to result in high attack rates among residents, staff members, and visitors. In the context of rapidly escalating COVID-19 outbreaks in much of the United States, it is critical that long-term care facilities implement active measures to prevent introduction of COVID-19. … Substantial morbidity and mortality might be averted if all long-term care facilities take steps now to prevent exposure of their residents to

4 CDC: COVID Data Tracker Weekly Review

5 New York State Open Data

6 U.S. Department of Health and Human Services, Office of Inspector General: Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23–May 30, 2020

COVID-19. The underlying health conditions and advanced age of many long-term care facility residents and the shared location of patients in one facility places these persons at risk for severe morbidity and death. Rapid and sustained public health interventions focusing on surveillance, infection control, and mitigation efforts are resource-intensive but are critical to curtailing COVID-19 transmission and decreasing the impact on vulnerable populations, such as residents of long-term care facilities, and the community at large.[7]

Within weeks, COVID-19 infection and death rates among New York State nursing home residents followed a similar trajectory as Washington State; see Table 1.

Table 1 – Number of Nursing Home Resident Deaths* Due to COVID-19 as of May 23, 2021

	Wave 1	Wave 2	Post-Wave 2	Total
	3/4/20–7/15/20	7/16/20–3/16/21	3/17/21–5/23/21	
Number of deaths	9,560	4,136	223	13,919

Note: We defined the ending of a wave as 7 or more consecutive days with a reported death total under 10 daily.
*Occurring both within and outside of nursing homes.

The Department is responsible for overseeing nursing homes, long-term care facilities, and hospitals (hereafter collectively referred to as facilities), and ensuring they comply with federal and State regulations, including infectious control requirements. Within the Department, the Division of Nursing Homes and Intermediate Care Facilities for Individuals with Intellectual Disabilities Surveillance (Division) is specifically responsible for nursing homes. Among other State/federal regulations, facilities are required to:

- Establish and maintain an infection prevention and control program, including a system for recording any incidents identified;
- Outline reporting requirements for outbreaks or significant increases in nosocomial infections (i.e., infections acquired in a health care setting, hereafter referred to as health care-associated infections);
- Possess and maintain a supply of all necessary items of PPE sufficient to protect facility personnel, consistent with CDC guidance (effective September 30, 2020, a 60-day supply); and
- Electronically report COVID-19 information (e.g., suspected and confirmed infections among residents and staff, resident and staff deaths, and PPE supply) in a standardized format.

In addition, throughout the pandemic, the Department, the Executive, and the federal government issued guidance on managing COVID-19 in nursing homes. For a timeline of major policies, see Exhibit A.

7 McMichael TM, Clark S, Pogosjan S, et al.: COVID-19 in a Long-Term Care Facility – King County, Washington, February 27–March 9, 2020. *MMWR Morb Mortal Wkly Rep* 69:339–342

The Department uses three systems for collecting and reporting infection control data, as follows (and as outlined in Exhibit B):

Nosocomial Outbreak Reporting Application (NORA). Facilities use NORA to report most health care-associated infection outbreaks. It is the Department's practice that reports made in NORA are to be triaged (assigned to a regional Department epidemiologist for review) within 2 business hours (Monday–Friday between 9:00 am and 5:00 pm). Regional epidemiologists work with the facilities to help end the outbreak.

Health Electronic Response Data System (HERDS). Facilities respond to HERDS surveys regarding a specific issue or public health emergency arising on a given day. Facilities also use the HERDS surveys to report COVID-19–related information and PPE. The Department uses HERDS to track facilities' PPE and ensure compliance with supply requirements.

Nursing home surveys. The Department conducts Standard Health (quality of care) and Life Safety Code (fire and safety) surveys, collectively referred to as Standard Health surveys. These are unannounced and must be conducted at least every 15 months. In addition, Complaint surveys investigate complaints and incidents reported by the nursing homes or third parties that may involve non-compliance with federal or State regulations. The Division's seven regional offices throughout the State, including three Metropolitan Area Region Offices (MARO) in the New York City area, carry out nursing home survey functions for nursing homes. Of the 618 nursing home facilities currently active in New York State, over half are located in the MARO area.

The Centers for Medicare & Medicaid Services (CMS) establishes the minimum requirements states must adhere to when conducting nursing home surveys. Requirements for conducting nursing home surveys are outlined in the State Operations Manual (SOM) issued by CMS. All information collected from nursing home surveys (e.g., deficiencies noted, deficiency category, violation citations, type of survey) are entered into a database maintained by CMS. According to the SOM, the Department may conduct nursing home surveys as frequently as necessary to determine if a facility is complying with CMS requirements as well as to determine if the facility has corrected any previously cited deficiencies. There is no required minimum time between nursing home surveys.

Effective March 4, 2020 through August 17, 2020, CMS suspended the requirements for Standard Heath and Complaint surveys not associated with immediate jeopardy, and directed states to instead conduct Focused Infection Control (Infection Control) surveys. Infection Control surveys use a streamlined review checklist of infection control activities to ensure providers have implemented actions to protect the health and safety of individuals and to respond to the pandemic. CMS' initial guidance did not stipulate a specific number of Infection Control surveys that states were required to complete. Due to inconsistencies among states in the percentage of nursing homes that were being surveyed (ranging from 11 to 100%), CMS revised its guidance on June 1, 2020 to require that all nursing homes in each state receive at least one Infection Control survey by July 31, 2020. Although CMS imposed a

minimum number of Infection Control surveys that must be conducted, states may choose to conduct additional Infection Control surveys as warranted.

If a nursing home survey reveals violations of federal or State regulations, the Department issues a statement of deficiencies detailing all violations identified. A range of deficiency categories are covered for each nursing home survey, including infection control. There are eight areas in which infection control deficiencies may be issued. The statement of deficiency has a corresponding federal tag numbering system that addresses the degree to which a facility meets federal standards. For each deficiency, surveyors use record reviews, interviews, and observations to determine both the scope and the severity of the issue based on CMS' rating system (see Exhibit C). Depending on the severity classification, the Department can implement a range of enforcement actions, such as directed plans of correction, fines, and, if warranted, facility closure.

Audit Findings and Recommendations

As the steward of the State's health program, the Department bears a responsibility to safeguard the health of New York's 20 million residents, to promote health through sound decision making and effective policies, and to lead the State's health program with integrity and transparency.

The sudden and daunting challenges that COVID-19 presented notwithstanding, we determined that, first and foremost, the Department was not transparent in its reporting of COVID-19 deaths at nursing homes. Particularly early in the course of the pandemic, the Department routinely underreported death counts, with its reporting at one point having an error rate of over 100%. All told, for the nearly 10-month period from April 2020 to February 2021, the Department failed to account for approximately 4,100 lives in nursing homes lost due to COVID-19. The Department's responsibility to accurately report is not only an ethical one but a moral one as well. In the face of its mission to advocate for the health and well-being of all New Yorkers, the Department's actions fell far short. Particularly in uncertain times, the public's trust and confidence in their leaders is of paramount importance in overcoming public health emergencies. The lack of transparency not only reduces confidence in the information being reported but also erodes the public's trust in the Department.

The Department collects a substantial amount of different data from NORA, HERDS, and its nursing home surveys – facility-related data that, analyzed collectively, can provide far more valuable information than merely the sum of their parts. However, the Department does not routinely analyze the data broadly, nor does it take advantage of certain other data sources, to detect interfacility outbreaks, geographic trends, and emerging infectious diseases or to shape its infection control practices and policies and its oversight of facilities. This inaction is contrary to its own guidance, which states that the reporting and collection of the data is important for these reasons. Such analysis might also allow the Department more effective use of the resources it has at its disposal for day-to-day operations and its response during public health emergencies. However, this is predicated on the fact that the data used for decision making is accurate and reliable. We found varying degrees of reliability (accuracy and completeness) with the data the Department uses, reducing its effectiveness for informed decision making and for promoting strong infection prevention and control policy recommendations.

The Department's limited oversight of nursing homes has been a long-standing issue. In a prior audit of *Nursing Home Surveillance* (2015-S-26), we found the Department's efforts went little beyond ensuring CMS' minimum standards are met. During our follow-up of that audit (2017-F-12), Department officials informed us that they had implemented a performance monitoring program to conduct greater oversight of nursing homes where conditions affect the rights, quality of life, or health and safety of residents. However, we learned that this program was simply a trial and had since been abandoned. The Department's lack of commitment to rectify issues and be proactive speaks to potential deficiencies in the overall control environment. Ultimately, given the events that transpired during the pandemic, we would expect the Department to utilize all available resources, including every source of data, and

strive to meet the highest level of oversight at nursing homes rather than settling for the barest minimum.

Finally, the Department imposed impediments on the audit, such as introducing delays in providing requested data, limiting auditors' contact with program staff, not addressing auditors' questions during meetings, and not providing supporting documentation. That we experienced these obstructions raises concerns about the control environment at the Department and does not support an overall sense of integrity and transparency.

As our audit evolved, the control environment was identified as a common denominator across our findings – a negative control environment that spawned systemic internal control deficiencies, thwarted transparency and accountability, and undermined the Department's mission and responsibility to the public. As supported by prior audits and various investigative reports, the Department was plagued by a threatening environment of intimidation, closed ranks, and lack of commitment to openness – at the expense of the public's trust.

The control environment has a pervasive influence on the decisions and activities of an organization and provides the foundation for the overall system of internal control. If this foundation is not strong—if the control environment is not positive—the overall system of internal control will not be as effective as it should be.

Reporting, Collection, and Use of Infection Control Data

Public Reporting

Providing access to government data engenders transparency and promotes public trust. While the Department's duty is to act solely to promote public health, we determined that, rather than providing accurate and reliable information during a public health emergency, the Department instead conformed its presentation to the Executive's[8] narrative, often presenting data in a manner that misled the public.

The Department's reporting of COVID-19–related nursing home deaths throughout the pandemic has consistently lacked transparency, and was at times inaccurate, inconsistent, incomplete, and/or not amenable to analysis.[9]

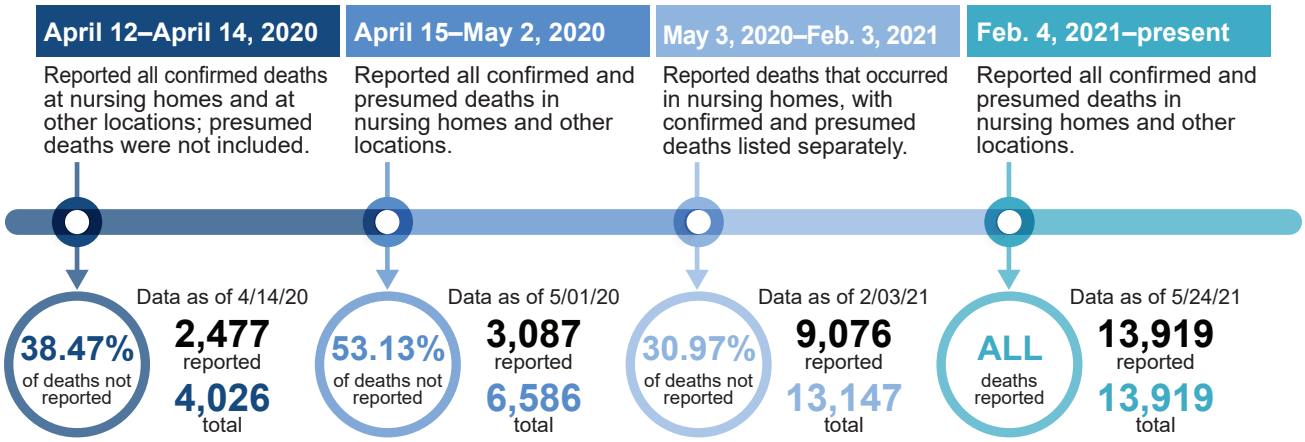
8 The Executive is defined to mean the former Governor, the members of his staff within the Executive Chamber, and the members of the New York State Interagency Task Force, including former health commissioner Howard Zucker.

9 The Department generally does not publicly report NORA data, although it is subject to the Freedom of Information Law. Regarding its nursing home surveys, while the Department does post this data online, not all data fields from the surveys are included, such as detailed violation citation information. Nursing home surveys are available in their entirety on a separate Department website, but only surveys from the last 4 years are posted and the format is not easily analyzable/searchable. Limiting the information available to the public, the ease of navigating, and the practicality of the format are detrimental to transparency and accountability.

When the Department first started collecting information about deaths in nursing homes, data accuracy was poor; however, even as data accuracy improved, the Department consistently underreported the total number of nursing home deaths to the public until February 4, 2021. Throughout the pandemic, the Department used alternating methodologies to account for nursing home deaths, with varying levels of accuracy and completeness and, as shown in the following figure, collectively accounting for a total of 4,071 deaths not reported prior to the Department correctly reporting all deaths as of February 4, 2021.

Timeline of Changes to Reporting Methodology

The Department varied its method of publicly reporting COVID-19 deaths in nursing homes, as shown in the following timeline. (Note: The death counts were calculated using the date the deaths were reported to the Department, not the actual date of death.)



Initially, when the Department started first reporting data to the public (April 12–April 14, 2020), it included all confirmed deaths by county at all nursing homes and at other locations. For the next 18-day period April 15 to May 2, 2020, the Department added reporting of presumed deaths by county as well as both confirmed and presumed deaths by individual facility – but only if the facility had five or more deaths. Thus, over 50% of the deaths that should have been reported at the end of that period were not – an error rate of over 100%. Subsequently, from May 3, 2020 to February 3, 2021, the Department excluded deaths that occurred at other locations and separated confirmed and presumed deaths, failing to report about 30% of the total COVID-19 nursing home deaths at the end of that period – a 45% error rate. When questioned, Department officials could not specifically explain the reason for the discrepancies. They stated, however, that, at that time, the numbers were constantly changing due to the frequent reconciliations being performed on the number of deaths reported, and that the numbers reported publicly were the deaths that had been reconciled with external data. However, the uncertainty of the numbers was not disclosed to the public. Also, this information, while available online, is in PDF format, which, as with the nursing home survey data, limits its usefulness.

When asked for their reasoning for the lack of consistency and a confirmation of our reporting timeline, officials only stated that they did not engage in decision making

related to public reporting, and that decisions on how to report death data are made by officials outside those collecting the data. They did not further clarify who these decision makers were.

However, despite Department officials' vague responses, documents and reports released as a result of various investigations, coupled with documents received from the Department as well as others that are publicly available, shed additional light on some of these decisions.

On March 9, 2020, Department officials began issuing HERDS surveys related to COVID-19. However, those initial surveys did not ask about COVID-19 deaths. Rather, officials obtained information related to deaths through telephone calls to each facility. On March 17, 2020, the Department first added a question related to deaths: "As of today, how many residents of your nursing home facility have been removed from your census due to death from COVID-19 in a hospital." That initial question did not ask for information about individual cases and it excluded deaths that occurred at nursing homes; Department staff continued to collect that information through phone calls. By all accounts, including our own review of the data, this reporting mechanism resulted in inconsistencies and inaccuracies. However, there was reluctance to admit this publicly. For instance, according to a report issued to the New York State Assembly Judiciary Committee,[10] sometime in April 2020, after releasing this data publicly, employees of the Executive Chamber and members of the New York State Interagency Task Force (Task Force), a group of senior-level administration officials whose role was to coordinate with local governments and health care partners to monitor and respond to the outbreak, became aware that certain fatalities were not being included in the published data – specifically that, for several weeks, deaths reported after 5 pm were not being included in the daily totals for certain facilities. The report notes that "there was some reluctance to admit error when it was discovered and to correct the published numbers immediately." Specifically, the report cites a Task Force member, when made aware of the issue, "saying something to the effect of, 'Do you want me to admit that we have been reporting deaths incorrectly?' "

Department officials felt they could not freely speak up regarding concerns during the COVID-19 pandemic if their opinion was contrary to that of the Executive and that speaking up could result in an even more limited ability to provide advice going forward.[10]

On April 14, 2020, the CDC issued new guidance redefining what constitutes a COVID-19 death, stating that death counts include both confirmed and probable deaths. The next day, the former Governor pledged to contact facilities and provide presumed death counts as soon as possible.[11] Based on our review of the cumulative data reported up to April 15, some facilities had already been reporting presumed deaths, but it was inconsistent. As of this date, public reporting included presumed deaths if the facility included this information, where it previously did not.

10 Impeachment Investigation Report to Judiciary Committee Chair Charles Lavine and the New York State Assembly Judiciary Committee, Davis Polk & Wardell, LLP, November 22, 2021

11 Andrew Cuomo, New York COVID-19 Briefing Transcript, April 15, 2020

Around this time, the Department constructed a new HERDS survey, which was first required to be completed by facilities on April 16, that asked not only about deaths at hospitals but confirmed and presumed deaths at facilities as well, eliminating the need for phone calls as the primary source of death information.

On April 15, the Department Commissioner held a conference call with nursing home operators, instructing them to start reporting in-facility deaths from COVID-19 within HERDS. In addition to confirmed cases, he asked them to include presumed COVID-19 deaths. Thus, deaths reported by nursing homes from April 15 onward should have included both confirmed and presumed deaths occurring at all facilities. On April 17, the Department issued a retrospective survey about all previously reported deaths, asking facilities to amend and correct prior data submitted.

On May 3, 2020, the methodology for reporting deaths changed to exclude deaths occurring in other locations and to begin listing confirmed and presumed deaths in nursing homes separately. Between May 2 and May 3, total deaths reported increased by 1,726.[12]

Articles from the news media at that time reported that this increase was due to the "the previously undisclosed deaths of more than 1,600 people who were presumed to have died of the virus at nursing homes but who had not received a confirmed diagnosis."[13]

However, while many presumed deaths were added, so were many previously unreported confirmed deaths. For example, the first nursing home listed on the May 2 report (the last report prior to the change in methodology) had a publicly reported total of six deaths as of May 1, 2020. However, according to HERDS, the actual number was 55 (19 confirmed and 36 presumed). Even excluding presumed deaths, the reported number undercounted confirmed deaths by over 200% (see Table 2).

12 Reports reflect data up to and including the previous day (e.g., data that is reported on May 2 includes deaths that occurred up to and including May 1).

13 From April 16 to May 2, the Department reported all nursing homes with five or fewer deaths, stating "[s]ome nursing homes include presumed COVID-19 deaths as well as confirmed COVID-19 deaths."

Table 2 – Nursing Home 1: Death Counts in HERDS vs. Counts Reported

	Deaths in HERDS 3/3/20–5/1/20	Deaths Reported as of 5/1/20	Deaths in HERDS 5/2/20	Deaths in HERDS 3/3/20–5/2/20	Deaths Reported as of 5/2/20
Total	**55**	**6**	**0**	**55**	**40**
Confirmed	19	NR	0	19	4
Presumed	36	NR	0	36	36
Hospitals/Other					
Confirmed	16	NR	0	16	NR
Presumed	0	NR	0	0	NR
Nursing Homes					
Confirmed	3	NR	0	3	4
Presumed	36	NR	0	36	36

Note: NR = not reported.

The second nursing home listed on the May 2 report showed six deaths for the period March 3, 2020 to May 1, 2020. However, HERDS reported 12 fatalities – all confirmed for this period – a 100% undercount (see Table 3).

Table 3 – Nursing Home 2: Death Counts in HERDS vs. Counts Reported

	Deaths in HERDS 3/3/20–5/1/20	Deaths Reported as of 5/1/20	Deaths in HERDS 5/2/20	Deaths in HERDS 3/3/20–5/2/20	Deaths Reported as of 5/2/20
Total	**12**	**6**	**1**	**13**	**10**
Confirmed	12	NR	1	13	10
Presumed	0	NR	0	0	0
Hospitals/Other					
Confirmed	3	NR	0	3	NR
Presumed	0	NR	0	0	NR
Nursing Homes					
Confirmed	9	NR	1	10	10
Presumed	0	NR	0	0	0

Note: NR = not reported.

The May 3 changes masked the correction of previously inaccurate death counts, which as of May 1 excluded 3,499 deaths, and resulted in only half of these undercounted deaths being reported. Moreover, while officials repeatedly justified

this change because of accuracy issues[14] – specifically potential double-counting – we found this was not the case. Comparing what was reported on May 3, 2020 to the contemporaneously "audited" HERDS data, the difference is only approximately 2%. Table 4 illustrates the total number of nursing home deaths as of May 1 and May 2, 2020 per HERDS data compared to what was reported.

Table 4 – Nursing Home Deaths as of May 2, 2020 per HERDS Data

	Reported 5/2/2020 (up to and including 5/1/2020)			Reported 5/3/2020 (up to and including 5/2/2020)		
	HERDS Count	**Included**	**Reported Separately**	**HERDS Count**	**Included**	**Reported Separately**
Nursing Homes	**4,612**	**Yes**	**No**	**4,699**	**Yes**	**4,813**
Confirmed	2,114	Yes	No	2,183	Yes	2,274
Presumed	2,498	Yes	No	2,516	Yes	2,539
Hospitals/ Other	**1,974**	**Yes**	**No**	**1,998**	**No**	**NR**
Confirmed	1,974	Yes	No	1,998	No	NR
Presumed	0	NR	No	0	No	NR
Total	**6,586**	**3,087**		**6,697**	**4,813**	

Note: NR = not reported.

Moreover, an addition of 3,499 new deaths to the count would have also impacted New York's standing compared to other states – decreasing the State's performance on several metrics related to nursing home deaths.

New York, according to a June 2020 news report,[15] saw 21% of its death toll occurring in long-term care facilities and was ranked 46th in the nation—meaning that 45 states had a greater share of fatalities within these facilities. With the inclusion of out-of-facility deaths, New York would have been closer to the middle. This statistic was repeated without necessary qualifiers in the Department's July 6, 2020 report, "Factors Associated with Nursing Home Infections and Fatalities in New York State During the COVID-19 Global Health Crisis," to tout New York State's performance, despite the fact that members of the Executive – who were involved in editing the report – should have been aware that New York State data was not comparable to other states[16] because it excluded out-of-facility deaths. This exclusion

14 New York State Senate Virtual Joint Public Hearing: Residential Health Care Facilities and COVID-19 – New York City, Long Island and Westchester; New York Gov. Andrew Cuomo COVID-19 Press Conference Transcript January 29, 2021 (01:00:03)

15 "43% of U.S. Coronavirus Deaths are Linked to Nursing Homes," *New York Times*, June 27, 2020

16 According to the Assembly Impeachment Investigation Report, the former Governor directed officials from the Executive Chamber, Task Force, and the Department to prepare a report from the Department

had the effect of diminishing other states' performance compared to New York and was misleading. Moreover, this analysis was not of nursing homes alone but of various long-term care facilities, as was reflected in its original title, "Cases and Deaths in Long-Term Care Facilities, by State." This title was subsequently changed by the authors to "Cases and Deaths in Nursing Homes, by State," further obscuring the lack of comparability of the data.[17] Even so, this data garnered its own appendix within the report with all states listed and was repeated multiple times by the former Governor.[18] This disingenuous presentation was not restricted to this one instance: another appendix in the same report that used the same data not only failed to clarify these differences but included incorrect data regarding a state that performed better than New York on another metric, which made it appear, incorrectly, that New York ranked higher than that other state on that metric.[19] Neither of these appendixes were corrected when the report was reissued in February 2021, although the complete data (including deaths at nursing homes and other facilities) was publicly available at that time.

According to the Assembly Impeachment Investigation Report, Department officials were concerned that this report was "directed by the Executive Chamber and Task Force, and was not in fact a scientific or medical report," and noted that while "DOH employees' most pressing concerns regarding drafts of the DOH Report were addressed prior to publication, other concerns with the nature of the DOH Report remained."

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in order to combat criticism of the March 25 Directive. The March 25 Directive dealt with the admission or readmission of nursing home residents who had been diagnosed with COVID-19. The Task Force was largely comprised of senior administration officials who were non-medical experts but did include the Department's Commissioner. We did not examine the validity of the medically related claims made but rather reviewed the presentation of the infection control data – the subject of this audit.

17 Appendix A – Nursing Home Facilities, by State – defined nursing home facilities as "Certified Nursing Facilities." According to the source of Appendix B data, the analysis included long-term care facilities, which encompasses nursing homes, assisted-living facilities, memory care facilities, retirement and senior communities, and rehabilitation facilities. The two are therefore not equivalent. While Appendix B stated that the "analysis included long term care facilities," it did not define this term. As there was some variability regarding what long-term care facilities each state reported, the data was not comparable.

18 This was repeated by the former Governor at press events to reporters ("Cuomo Defends Nursing Home Policies After Saying He's Saved Lives During Pandemic," *Finger Lakes Daily News*) and included in his book *American Crisis: Leadership Lessons from the COVID 19 Pandemic*, page 230.

19 In Appendix C – Nursing Home Fatalities as a Percentage of Nursing Home Residents and General Population – while the data used to calculate the metric for Nursing Home Fatalities as a Percentage of Nursing Home Residents was included in the table, the metric was not calculated but the data was provided (# of Deaths/Total Nursing Home Residents). For Pennsylvania, the number of nursing home residents was incorrect. In Appendix A, Pennsylvania's number of nursing home residents is 76,652, which is approximately the number reported by the State itself. However, in Appendix C, the number given is 20,689. Using the correct data, Pennsylvania's Nursing Home Fatalities as a Percentage of Nursing Home Residents was 5.89%. New York's was 6.34%. Pennsylvania would have performed better than New York and, rather than New York, would have been first of the five states listed. With the erroneous data presented in the report, Pennsylvania's Nursing Home Fatalities as a Percentage of Nursing Homes Residents was 21.84%, making it falsely appear that Pennsylvania performed significantly worse that New York.

Additional statements made to tout New York's performance in other published documents were also questionable, such as the claim that, even before a single person had died of COVID-19 in New York, nursing home staff were required to wear masks, and that no visitors were allowed except in limited circumstances.[20] New York provided this guidance on March 13, and while the State's first publicly reported death occurred on March 14, HERDS data shows that the State's first nursing home death was 11 days earlier on March 3. In total, nine nursing home fatalities – all presumed – occurred prior to the State instituting these guidelines. This information, while not publicly available, was available to the Department and, by extension, to the Executive.

This apparent willingness to mislead the public is suggestive of the significant communication and control environment deficiencies that were ongoing at the Department throughout the COVID-19 pandemic. Many of these issues were highlighted in the November 2021 Assembly Impeachment Investigation Report, in sworn testimony to the Attorney General by a Department staff member pursuant to another matter, and in myriad press accounts – and affirmed by our own observations. Collectively, these reports paint a picture of an Executive that was micromanaging with top-down decision making on every matter, regardless of size, and tight control over information. Further, according to the Assembly report and other sworn testimony, there were concerns by Department officials that the Task Force was largely comprised of non-medical experts, whose decisions were not always made based on scientific or medical advice – but whom Department health experts nevertheless often had to defer to.[21]

While the Executive has a clear role in regard to overall coordination and communication efforts in such emergencies, the Department also has a role due to its staff's expertise. This includes providing leadership and guidance to local health departments. Local (county) health departments are the "boots on the ground" that help the Department respond to outbreaks and are critical for mitigating the spread of infection. Many of the activities needed to slow the epidemic and minimize its impact on communities are performed by the counties. However, Department officials were prevented from fully performing this fundamental role due to the environment created by the Executive.

During the audit, officials from the counties, including the New York City Department of Health and Mental Hygiene (DOHMH), noted serious communication deficiencies on the part of the Department. They stated that, among other issues, many of their primary infectious disease contacts had left the Department and counties that normally collaborate and act as partners during such events were "not in the loop." When the local officials called the Department for information, the few contacts who would speak to them would "backchannel" information as they were not allowed to officially speak with them. County officials also stated that the Department would arrive on site at the county departments but would not share information on their

20 *American Crisis: Leadership Lessons from the COVID 19 Pandemic*, page 59

21 Impeachment Investigation Report to Judiciary Committee Chair Charles Lavine and the New York State Assembly Judiciary Committee, Davis Polk & Wardell, LLP, November 22, 2021

activities – even to those county officials responsible for administering policy at the local level. Other officials stated that communications directly from the Department were inconsistent, particularly during the early months of the COVID-19 pandemic. Information came from multiple sources, such as official communications via the Health Commerce System, press releases issued by the Executive, and documents that would be posted inconspicuously and without fanfare to the State's various websites. Outside of advisories and alerts via the Health Commerce System, the Department did not provide guidance on data collection and reporting, and throughout the pandemic, DOHMH and the Department did not have matching data for the same metrics. In addition, many of these advisories and alerts were received after New York City was already experiencing and dealing with the issue on the ground in real time. Officials noted that routine, staff-level communications with the Department were not helpful as they were not able to answer questions about the guidance, solicit or incorporate feedback from the local level, or give them advanced notice prior to the public release of information.

This scenario of deficient communication was confirmed by the Department's former Director of Epidemiology, in sworn testimony[22] for a separate Attorney General investigation:

> Normally we keep healthcare providers abreast on for the issues, they are the ones educating patients and their communities across the state. We send out advisories and updates and informational message to 100,000 plus healthcare providers, doctors, nurses, nurse practitioners, school nurses, universities, health centers and we normally send out these updates regularly. These were not allowed to be sent out. … We also would work closely with all of these partners through their association when it comes to healthcare providers because it is hard to work with each one obviously and then through the local health department would look to us for guidance and information so that things could be standardized across counties and they could have support in doing their implementation of public health on the ground. But we weren't really able to communicate with them openly as we normally would or send out information and updates as we normally would. These were things that had to go through approval and would either not be approved or it would take so many months it was quite out of date and irrelevant by the time the approval was received.

The Department's reporting and communication strategies deviate significantly from that of other states. For example, according to officials from both Washington State and North Carolina, they had continuous ongoing and open communication with their localities and utilized a centralized reporting system. In addition, deaths that occurred in nursing homes were always consistently reported, including presumed and confirmed deaths, because it was based on the resident's home address (i.e., the nursing home), not where the death occurred.

22 In the Matter of the Independent Investigation Under Executive Law 63(8), May 24, 2021 Testimony of State Entity Employee #2

External communication with outside parties is essential to effective internal control. Management should consider a variety of factors when selecting an appropriate method of communication, including the audience and the nature of the information provided. Inconsistent reporting reduces the usefulness of information to external stakeholders such as the public. Combine this with little explanation of the inconsistences, quality issues, and tight controls on both information and message by the Executive, it is not surprising that transparency, accountability, and public confidence in the information being reported all suffered.

Data Collection and Use

The Department, to meet federal and State requirements, collects a substantial amount of information from NORA, HERDS surveys, and nursing home surveys. However, the Department does not fully utilize and analyze this data collectively to shape infection control practices through policy recommendations or nursing home survey actions. None of the data is analyzed, either alone or in connection with other data, on any routine basis to detect interfacility outbreaks, identify geographic trends or emerging infectious diseases, or promote changes in infection control policy recommendations, despite the Department's own guidance specifically stating that the reporting and collection of data is important for these reasons.

According to Department officials, the main purpose of NORA (other than to meet federal and State requirements) is to alert regional Department epidemiologists of an incident at a specific facility so they can work with the facility to end the outbreak. Officials also stated that it is difficult to use NORA for future forecasting due to the dependence on external facilities to report incidents through NORA and to report accurate data. Furthermore, the Department has been aware that certain facilities were failing to report incidents through NORA at least since 2015 but has not followed through on plans to address this issue.[23]

As the Department itself noted, "Timely and complete reporting of communicable diseases is critical for NYSDOH response activities."[24] Early in the pandemic, there were only 13 reported instances of COVID-19 in NORA between March 1 and March 15, 2020, and 163 instances reported between March 16 and March 31, 2020. During this time period, HERDS data shows 705 fatalities at 160 different facilities, pointing to a likely significant underreporting of infections and outbreaks within NORA.

In King County, Washington, after its first case of COVID-19 in a nursing home was identified, countywide databases of emergency medical service transfers from long-term care facilities to acute care facilities were reviewed daily for evidence of cases or clusters of serious respiratory illness. Routine active surveillance reports for flu-like illness clusters from long-term care facilities were employed to identify clusters of illness consistent with COVID-19. Based on this information and an email survey, long-term care facilities were prioritized by risk for COVID-19 introduction and spread, and highest-priority facilities were visited by response personnel for provision of emergency on-site testing and infection control assessment, support, and training.[7]

23 New York State Healthcare-Associated Infections Action Plan, December 15, 2015

24 Outbreak Reporting By Hospitals and Nursing Homes - New York State, 2010-2015 (abstract), presented at the 2017 Council of State and Territorial Epidemiologists Annual Conference

Although the data is used for limited purposes, we found the Department is generally meeting its practice of triaging NORA reports within 2 business hours. Of the 7,757 reports entered into NORA between January 1, 2017 and December 15, 2020, we reviewed 7,716 and found, with limited exception, that they were all triaged on time.

As with NORA data, we did not see evidence that the Department used HERDS data in conjunction with other data sets such as NORA or nursing home survey data to influence infection control policy recommendations.

While the Department can produce exception reports to determine if a facility fails to submit a daily HERDS survey, the Department uses the HERDS data for limited purposes (outside its use for public reporting). Officials stated that they use the data to identify facilities that have unusual spikes in deaths, but did not provide any documentation for what follow-up actions they take on behalf of these facilities or what constitutes a "high spike." Department officials also did not provide any documentation showing a structured effort to use the data to influence infection control policy recommendations. Officials stated they were not planning on reviewing nor do they routinely review the data to determine trends, interfacility outbreaks, geographic trends, and other factors of potential value. Rather, officials stated they use the HERDS survey information in real time to triage issues as needed and see no value in looking at historical data.

The Department used facilities' responses to the HERDS surveys to adjust questions on future surveys to capture additional needed information. The Department modified the HERDS survey questions and fields throughout the COVID-19 pandemic to collect information such as the number of confirmed COVID-19–positive residents, number of N-95 masks on hand, number of employees who worked at the facility on a given day, and information related to COVID-19 deaths (e.g., date and place of death).

Department officials use HERDS survey data to track facilities' levels of PPE on hand and, as applicable, to assist them in obtaining additional PPE pursuant to CDC guidance. The Department measures PPE weekly and maintains a manual spreadsheet of low supply at facilities. When a facility is found to be below the compliance levels twice, enforcement actions, such as suspension of the facility's license, can begin. Despite the September 30, 2020 compliance date, the Department did not begin any enforcement actions until December 2020. Officials responded that this was an upper-management decision and provided no further explanation. As of October 2021, no enforcement actions have been fully resolved from over 200 violations cited at nursing homes (we only received information on violations at nursing homes, not at other facilities).

While utilizing data, such as HERDS survey data, to better react immediately during an emergency is useful, as the COVID-19 pandemic began to span months and into years, the Department has not adjusted how it utilizes the vastly amassed data to its fullest potential as a tool for shaping infection control practices. Similarly, the Department has not adjusted how it incorporates and uses nursing home survey data in conjunction with other data sets when conducting nursing home surveys. Although

the SOM outlines basic minimum requirements, it does not specifically restrict the factors states may use when determining what constitutes a poorer-performing or riskier nursing home for the purpose of conducting nursing home surveys. This allows the State flexibility to build in any number of risks when determining how and when to conduct surveys – including utilizing other Department sources of data in conjunction with nursing home survey data.

Analyzing and collectively using data on a broader scale could be an effective tool to assist in directing resources during an outbreak. For example, we analyzed NORA data and found a moderately strong positive correlation of 0.61 (on a scale of -1 to 1 with -1 being a strong negative relation, 0 being no relation, and 1 being a strong positive relation) between flu and COVID-19 outbreaks at facilities reported between January 1, 2017 and December 15, 2020. Incorporating this relationship when shaping nursing home survey efforts – to facilities with the highest correlation between the two – might have been useful prior to, during, and after the COVID-19 pandemic when the Department needs to determine where to focus efforts to manage outbreaks at nursing homes, even taking into consideration the data's limitations.

Through various nursing home surveys, the Department collects a large amount of information on the historical performance of nursing homes, such as citations and fines issued for infection control deficiencies and other categories and complaints made over years of operation. Deficiencies captured under infection control may include failure to establish and maintain an infection prevention and control program, not practicing proper hand hygiene, improper use of PPE, and so on. However, the Department uses this data in limited ways to shape infection control practices.[25]

Department officials stated they use nursing home survey data to determine whether they should: consider more stringent corrective actions from one survey to the next; issue fines; and conduct more frequent surveys. However, we did not find evidence that the Department incorporates use of any of these data sets into a risk assessment for nursing home survey efforts – which may include the timing and frequency of conducting surveys. According to the U.S. Department of Health and Human Services Office of Inspector General's report "Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23–May 30, 2020," other states used nursing homes' prior deficiency citations to target their mandated Infection Control surveys during COVID-19, with one state giving top priority to nursing homes with a history of multiple infection control deficiencies. California was even more proactive, developing a dashboard to identify high-risk facilities for on-site surveys and later forming a "strike team" to survey nursing homes with urgent problems. Using predictive analytics, California created a list of high-risk facilities, calculating risk by using deficiencies cited, proximity to hot spots, and other factors.

25 Officials stated that, although they generally use the nursing home survey data in those ways, there is no written policy that provides specific direction. The SOM does not specifically speak to how states should use their nursing home survey data, and the Department has not issued guidance to its staff.

In response to our preliminary findings, Department officials also stated that various data sets are used to identify trends and to inform the Department and key stakeholders on the various policy decisions that have been made throughout the COVID-19 pandemic. Despite our requests, the Department did not provide us with any support for these assertions.[26]

Generally, we found the Department ultimately defers to CMS for instruction on when and how to alter nursing home survey actions, which shape infection control policy. The Department artificially limits its actions by relying almost exclusively on CMS' direction, although the SOM allows the State discretion in executing survey activity as it meets CMS minimum standards.

The Department does have a policy outlining how nursing home survey results should be used and to determine if nursing homes with violations should be fined. However, fines represent a relatively small percentage of the enforcement action the Department utilizes. Of the 14,483 citations issued for the period September 1, 2017 through August 17, 2021, only 301 instances resulted in a fine. As noted in our previous audit of the Department's *Nursing Home Surveillance* (2015-S-26), the Department favors other enforcement actions such as corrective action plans. In that audit, we recommended the Department consider assessing fines more frequently at facilities that demonstrate a pattern of repeated citations. In our follow-up (2017-F-12), the Department noted it had implemented a performance monitoring program to conduct greater oversight of nursing homes where conditions affect the rights, quality of life, or health and safety of residents. However, we later learned that this program was simply a trial and was discontinued shortly after the follow-up was issued. This lack of commitment to rectify issues identified in the prior report again speaks to potential deficiencies in the overall control environment.

Prior to the COVID-19 pandemic, and excluding Infection Control surveys, citations for infection control deficiencies nationally were very high. A 2020 report from the U.S. Government Accountability Office found that infection prevention and control deficiencies were the most common type cited in surveyed nursing homes, with most nursing homes having an infection prevention and control deficiency cited in one or more years from 2013 through 2017. This trend continued in 2018 and 2019, with about 40% of surveyed nursing homes having an infection prevention and control deficiency cited each year. Similarly, for New York, in 2019 approximately 39% of nursing homes surveyed were cited for infection prevention and control deficiencies, with 25% of these facilities also having been cited in the prior year (38% of the 2019 facilities with deficiencies were not inspected in 2018).

To determine the Department's enforcement efforts during the pandemic, we requested data pertaining to inspection reports, complaint and incident summary reports, enforcement summary reports, and deficiency-related reports. Department officials only provided information that was on its website, stating they could not

26 Officials provided us with a heat map developed from HERDS data that shows newly diagnosed cases each week and confirmed cases at each nursing home. However, officials did not give us details or support for how the map was used, documentation of who and how it was shared with internal or external parties, or how specifically the resulting map affected nursing home survey activity.

provide us with data from CMS' system without permission from CMS, which officials stated they did not obtain. The data from the Department's website does not include enough detail to determine how the Department applied its enforcement policy and imposed fines based on the citations the nursing home received. We could not test whether surveyors consistently applied more stringent enforcement based on prior citations because the information provided did not cite the specific citation for each nursing home survey. The Department did complete the required Infection Control surveys as directed by CMS and issued 602 violations as of August 16, 2021, but only 189 (31%) show dates of correction for these deficiencies.

Due to the limitations in the data available to us, we analyzed data from CMS' website to determine the frequency of infection control issues found during the Department's Standard Health and Infection Control surveys. This data shows 461 infection control citations were issued from February 8, 2016 through March 3, 2020 and 307 citations from March 4, 2020 through September 23, 2021. The data available online includes the full inspection text for each citation issued. Based on a search of key words such as "PPE," "linen," and "legionella" and the number of citations where each key word occurred within the inspection text, we determined that improper hand hygiene, improper use of gloves, and improper wearing of masks were the most frequently mentioned issues. The Department could perform a similar or better analysis (given its access to more complete and detailed data) to identify what and where the most prevalent issues are and provide targeted training to help mitigate them; however, as previously mentioned, the Department does not proactively exploit the data or resources at hand for more granular analysis.

We also reviewed how many nursing home surveys were completed by the Department throughout our scope period. Table 5 gives a breakdown of surveys completed over various time periods, based upon a listing of each type of survey provided by the Department.

Table 5 – Breakdown of Surveys Completed Over Various Time Periods

Survey Type	Pre-COVID-19 Pandemic	COVID-19 Pandemic	First Spike*	Second Spike**	After Spikes	First CMS IC Survey Request	Second CMS IC Survey Request
	9/1/17–3/3/20	3/4/20–7/9/21	3/4/20–4/20/20	4/21/20–1/11/21	1/12/21–7/9/21	3/4/20–6/1/20	6/2/20–7/31/20
Standard Health	1,115	158	14	64	80	15	0
Complaint	8,250	4,037	128	2,478	1,431	485	806
Infection Control	0	2,628	21	2,011	596	336	863
Totals	**9,365**	**6,823**	**163**	**4,553**	**2,107**	**836**	**1,669**
Deaths	**1**	**13,918**	**5,652**	**6,529**	**1,737**	**9,191**	**476**

Note: IC = Infection Control.
* Ending date with the highest number of deaths reported in HERDS for 2020.
**Ending date with the highest number of deaths reported in HERDS for 2021.

According to the U.S. Department of Health and Human Services Office of Inspector General's report,[27] the Department had surveyed only 3% of nursing homes in the first month following CMS' directive, and by May 30 had only performed Infection Control and Complaint – immediate jeopardy surveys for 20% of nursing homes between March 23 and May 30, 2020, compared with over 90% for other states.

In fact, we found the Department generally waited to conduct a majority of its Infection Control surveys until CMS issued the July 31 requirement, conducting 2.5 times as many Infection Control surveys after June 2 than it did before then. The June 1 directive required states to complete infection control inspections of all nursing homes by the end of July 2020 to receive all their CMS-allocated CARES Act funding. Such inspections may have provided valuable information to facilities. CMS reported that the initial surveys conducted during the week of March 30 found 36% of facilities inspected did not follow proper handwashing guidelines and 25% failed to demonstrate proper use of PPE. Both are established infection control measures that all nursing homes are expected to follow per federal regulation. For information to be relevant to officials, it must come from reliable internal and external sources in a timely manner. Waiting to conduct a majority of the Infection Control surveys until 3 months into the COVID-19 pandemic may have reduced the usefulness of Infection Control surveys and the data therein to inform infection control practices early on in the pandemic.

Department officials stated they met the required time frame (at least every 15 months) for conducting Health Safety surveys. However, we determined that, before Health Safety surveys were suspended, 396 facilities had gaps greater than 16 months between surveys, including 107 with gaps of more than 20 months.

27 U.S. Department of Health and Human Services, Office of Inspector General: Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23–May 30, 2020

Officials also stated they met the Complaint survey requirements 98.3% of the time for immediate jeopardy complaints, 17% for non-immediate jeopardy high-priority complaints, and 29% for non-immediate jeopardy medium-priority complaints, and they perform non-immediate jeopardy complaint investigations as part of their recertification surveys. However, they also acknowledged difficulties meeting complaint time frames in the MARO office due to volume and staffing.

Based on prior audit findings, we have discerned a pattern by the Department of focusing on meeting minimum standards rather than ensuring that programs' objectives are met. For instance, in our report *Oversight of Resident Care-Related Medical Equipment in Nursing Homes* (2016-S-80), while the Department's sample sizes of equipment selected for testing and inspection met federal requirements, the numbers were disproportionately small relative to the actual number of equipment items in the facilities, and potentially inadequate to identify equipment deficiencies, particularly at facilities with a history of poor nursing home survey results.

Officials also identified staffing shortage as a factor that affected their ability to complete nursing home surveys across the State, including pushing more out to beyond 15 months than before. Staffing levels for employees conducting nursing home surveys have remained relatively flat since 2017 despite having trouble meeting requirements. Therefore, when the COVID-19 pandemic started, the Department needed to add over 30 temporary employees to meet the pandemic's needs. While the Department managed to meet its needs during the pandemic, this was a temporary solution. Incorporating the analysis of multiple data sets might allow the Department to use its resources more effectively.

Although not used by the Department, the CDC's Infection Control Assessment and Response (ICAR) tool would be a valuable additional data source to assist the Department in assessing a facility's infection prevention and control practices and guide quality improvement activities. The CDC developed the ICAR program in 2014 in response to lessons learned during the Ebola virus crisis. ICAR is an emergency preparedness program that helps health care facilities assess infection control practices and identify opportunities for improvement.

Officials stated they initially used the ICAR tool between 2015 and 2018, which was funded by the federal government and administered through Health Research, Inc. (HRI). Because the grant was administered by HRI, we did not have direct access to the terms of the contract between the Department and HRI, and were not aware of this program until an official from another state mentioned it as a key tool they use for infection control.

During that time, officials stated they performed 139 ICARs at facilities across the State (excluding New York City), but then discontinued systematic use of the tool after funding ran out. However, documentation provided by officials only shows 30 ICARs were performed from 2016 to 2018; 2015 data was not provided. Department officials further stated that when the COVID-19 pandemic struck, some regional staff tried to use the ICAR tool for both virtual and live site visits but found that it was impractical for facilities to complete. While states are not required to use the

ICAR tool, at least seven states currently list ICARs as a best practice to mitigate COVID-19 within nursing homes.

The Department did not provide us with the number of regional offices that attempted to revisit use of the ICAR tool, but some of the problems they encountered might have been due to lack of practice or inexperience. Officials from Washington State and North Carolina, who continuously used the ICAR tool before and during the COVID-19 pandemic, stated the ICARs were instrumental in providing detailed information on gaps in infection control during the pandemic. They used the data collected from the ICAR tool in conjunction with standard nursing home survey data to provide additional aid to facilities coping with the pandemic. Officials from Washington State, which was among the first states on the front lines of the COVID-19 battle, specifically stated that their combined use of the ICAR tool and other data sources (the use of which was noted in a report issued by the CDC on COVID-19 in long-term care facilities) was invaluable in managing COVID-19 outbreaks at the start of the pandemic.

Department officials also stated that, instead of using the ICAR tool, in March 2020, staff in the MARO office, with help from the CDC, developed an infection control and prevention assessment tool modeled after the ICAR tool. Called a COVIDeo checklist, it could be used for both virtual and live site visits. The initial pilot was from March 15 to March 28. However, at the time the pilot started, nine deaths in downstate nursing homes had already occurred. According to a journal article published by the Department on the pilot, of the 92 assessments conducted, 52 were done as part of COVID-19 investigations in facilities that had already reported COVID-19 infections and 40 were proactive assessments.

Of the proactive assessments, 35% identified suspected or confirmed COVID-19 cases. Thus, of the original 92 facilities in the pilot, 66 (or 72%) already had either a COVID-19 case or a suspected case. Staff used the COVIDeo checklist to conduct over 420 virtual assessments between March 15, 2020 and November 15, 2021. Officials stated that the checklist has evolved over time based on modifications/revisions of national and State response guidance. Based on the assessment examples provided by the Department, we found the COVIDeo tool pointed out not only issues found but also items that could lead to potential issues. Had the Department maintained a consistent ICAR program before the COVID-19 pandemic, it would have already had data on hand from previous work and been able to more easily transition the program to fit the needs of the pandemic.

In response to our preliminary findings, Department officials noted that they have taken other actions. For example, the Department implemented new requirements for COVID-19 testing and education as well as the offering and reporting of vaccination for nursing home residents and staff. The Department has also engaged nursing homes directly through regular provider calls. Department officials noted they made hundreds of daily follow-up calls to nursing homes with increased transmission, used video assessments to provide epidemiological recommendations to support strong infection prevention and control practices, and deployed a multitude of resources including guidance documents, pulse oximeters, PPE, and epidemiological support

to expeditiously combat the impact of COVID-19 in nursing homes. Results of daily HERDS surveys, combined with frequent calls to nursing homes and analysis of community spread data, have routinely been used to inform decisions and guidance on eye protection, quarantine protocols, enhanced testing of residents and staff, and provider education on proper infection prevention and control and the use of PPE.

Data Reliability

Data that is inaccurate or incomplete has reduced value for informed, effective decision making and for promoting strong infection prevention and control policy recommendations. We tested data reliability of the Department's three systems.

NORA

We found the information in NORA to be unreliable as it contained both inaccurate and incomplete data and potentially duplicate reports – that is, multiple, nearly identical reports submitted by a given facility on the same day. We received a listing of all NORA reports submitted to the Department with a reported date from January 1, 2017 through December 15, 2020, which totaled 7,757 reports. This listing included the facility name and location, type of infection, outbreak dates, triage dates, and number of cases for both patients and staff for each outbreak. We found several areas in which the NORA data contained inaccurate or missing dates. For example, 112 of the 7,757 reports had no triage date. In addition, 23 reports had triage dates that predated the reporting date, which is not possible. Department officials were able to correct these inaccuracies within NORA and provide the correct triage dates upon our request, but were unaware of the issue with these dates until we brought them to Department officials' attention.

Additionally, there were large discrepancies between the NORA data and CMS data on COVID-19 infections within nursing homes – which, if reported correctly, should match each other. The number of cases reported in NORA as of December 15, 2020 was much lower than that reported by CMS. For example, there were 18,807 confirmed patient cases of COVID-19 in CMS' data, but only 4,939 such cases in NORA – a difference of 13,868 cases. While Department officials noted that cases that are not officially closed within NORA would not show up in their data, they could not fully explain the reason for the discrepancy (i.e., whether it was an issue with data reported in NORA or reported to CMS, both, or neither). Therefore, we cannot conclude whether the data in NORA is complete or not – however, the significant discrepancy indicates NORA might be missing information.

Officials stated they had concerns regarding the completeness of the NORA data in the past, specifically related to underreporting of incidents. In 2013, they used one-time grant funding to hire staff to analyze the data and identify underreporting facilities. The analysis identified facilities that had not reported information in NORA in the prior 1 to 3 years. Officials stated they used this list to follow up with facilities about their lack of reporting. Based on this pilot, the Department concluded that the number of outbreaks that were reported increased after outreach by the Department

and that "[the Department's] efforts to contact facilities with low compliance should be continued, including assessment of the barriers to NORA reporting."[28] However, the Department did not follow through on this recommendation. While the Department still has access to the code used to generate the report and could run the report again to ascertain facility underreporting, the needed staffing resources are no longer available due to the grant's expiration.

The Department has provided training for facilities and issued guides on the technical aspects of how to use NORA (e.g., how to start a report, how to enter information). However, there has been limited guidance on what information facilities should report and how to report (e.g., when a new report should be created for an incident vs. updating an existing one), leading to inconsistencies and inaccuracies. Additionally, the Department performs limited data verification or validation on the information entered in NORA. There are no edit checks that would prevent issues such as triage dates that precede the date an outbreak was reported. The accuracy of reported NORA data is dependent almost solely on the reporting facilities. While the regional epidemiologist works with the facility and in some capacity corrects and verifies the data in NORA, the main priority of the epidemiologist is to work with the facility to end the outbreak, not ensure data quality. If facilities are continually uncooperative or there is unverifiable data, the Department may send staff to visit the facility, but there is no standard rule or policy regarding when this should happen.

HERDS

The accuracy of the information reported in HERDS varied throughout the COVID-19 pandemic. Officials generally acknowledge that, at the start of the pandemic until approximately mid-May 2020, there were significant data quality issues and limited controls to ensure accuracy of the data submitted in HERDS, including deaths reported in nursing homes. Even with the Department requesting retroactive data on April 17, 2020, accuracy issues remained. For instance, 24 of the dates of death were between 1 and 8 days after the day the death was reported. However, as the pandemic continued, the Department developed additional controls to improve accuracy.

While the Department heavily relies on facilities to correctly self-report information on each survey, it has developed some edit checks and performed some validation of the information reported in HERDS. For example, the Department initially used formulas within spreadsheets to try and identify obvious data errors in the HERDS surveys. However, by May 2020, it began using Statistical Analysis System rules to identify data errors. These rules create a report that Department staff use to contact nursing homes for explanations of any variances identified (e.g., death dates incorrectly entered as a date in the future, if at least 7 days old; fields reporting PPE on hand; testing results).

28 Outbreak Reporting By Hospitals and Nursing Homes - New York State, 2010-2015 (abstract), presented at the 2017 Council of State and Territorial Epidemiologists Annual Conference

The validation rules have evolved over the COVID-19 pandemic, allowing Department officials to add or modify them as needed. In response to our audit, officials stated they have also added more rules.

Although the accuracy of the data early in the COVID-19 pandemic was poor, the additional controls implemented by the Department as the pandemic has continued have improved upon this issue. Although officials at 34% of the facilities we tested (17 of 50) did not maintain documentation, for the 33 facilities we could test, the documentation generally supported the information submitted on the HERDS survey. The Department did not require facilities to maintain support for most of the fields in HERDS, which may be the cause of missing information.

Department officials indicated that, while they do not generally request supporting documentation for data reported on the HERDS surveys, they do request support for death data, and staff check the documentation against the information reported in the survey. While helpful to verify that the deaths reported occurred and were caused by COVID-19, this control would not detect if a facility omitted a death from the total reported on the HERDS survey. Officials stated they would only be able to verify whether death data was omitted when they conduct Infection Control surveys at the nursing home.

Specifically related to deaths, we selected 41 deaths to verify that the correct total was reported on the HERDS survey and that there was support for the death data. By the time of our testing, the facilities indicated that they no longer maintained sufficient documentation to support 17 of the deaths. For 22 of the 41 deaths reported in our sample, support confirmed that the information was accurately reported. The most notable errors we found were for information reported early in the COVID-19 pandemic – supporting that accuracy at that time was poorer than in later dates sampled. For deaths reported on April 18, 2020, one facility provided support for one death and not another; another provided a log of deceased patients rather than death certificates. This log provided support for two deaths on the date we requested information for, even though only one was reported in HERDs on that date, which raises questions about completeness.

We found that for the HERDS data most of the surveys were received and fields were completed. From April 16, 2020 to April 21, 2021, the Department issued a total of 225,939 HERDS daily COVID-19 surveys. Of these, 225,804 (99.94%) were submitted and fields were completed.

Nursing Home Surveys (Standard Health, Complaint, and Infection Control)

As mentioned earlier, the Department did not provide us with its nursing home survey data, citing CMS permission issues. Instead, we tested the data posted on the Department's website, which would have provided only limited assurance of the data's reliability. This data is removed and manipulated from CMS' database and limited fields are posted online: bed counts, citations, fines, facility ownership and

location, and surveys conducted. The fields include general deficiency category, severity, scope of residents affected, federal tag, survey type, initial survey date, correction date, and fine amount. Ultimately, our testing found the data posted publicly may not be entirely accurate, and we could not conclude whether the data was complete.

For 50 surveys posted, we tested all of the fields available on the Department's Open Data website against the most recent inspection reports posted on the Department's website, and found that 48 of the 50 matched. The other two had incorrect information in certain fields due to potential file corruption or other, unknown reasons. Also, we compared the Department's posted nursing home survey and citation data to CMS' public data, and found that the two data sets did not reconcile despite being pulled from the same system.

We also note that written communications from Department staff to auditors regarding the system and its capabilities were reviewed by management prior to being provided to the auditors. Because Department officials were unwilling to allow their staff to provide information directly to us without prior management review and clearance, we have limited assurance that the data presented was not altered or modified after we requested it. As a result, we considered that information to be less reliable in forming our audit conclusions.

Resources

New York's public health infrastructure – which is led by the Department of Health – helps to prevent disease, promote health, and prepare for and respond to emergency situations and other challenges. This work, as well as any cracks in the infrastructure, often goes unnoticed until there is a public health emergency.

The Department also plays a critical role in educating the public about sudden infectious disease threats as well as evidence-based mitigation. Adequate funding is necessary to provide these services.

Persistent underinvestment in public health over the last decade may have limited the Department's ability to prepare for and respond to any event – COVID-19 or otherwise – in the most effective way. Department staff, by all accounts, have worked tirelessly throughout the pandemic. However, better data and information systems and an established system of proactive infection control reviews for facilities prior to the pandemic would have provided them with more accurate and complete information early on to assist them in their work and would have helped facilities be better prepared.

Moreover, once the pandemic began, rapid and sustained public health interventions, including surveillance, infection control, and mitigation efforts, were critical to curtailing COVID-19 transmission to decrease the impact on vulnerable populations, such as nursing home residents, and the community at large. However, such efforts are resource-intensive, and it is clear that the Department was not adequately equipped in this regard.

According to the CDC:

> Decades of underinvestment has undermined the public health workforce. With diminished funding, state and local health departments have not been able to attract, recruit, and retain the number of professionals with skills needed to respond to health threats. … The COVID-19 pandemic highlighted the consequences of this underinvestment, and the critical need for a strong and diverse public health workforce.[29]

While other factors, such as the control environment issues previously discussed, no doubt have played a role, it is our judgment that this persistent underinvestment significantly contributed to many of the conditions identified within this report.

Recommendations

To the Department:

1. Develop and implement policies, procedures, or processes to:
   - Expand use of infection control data, including but not limited to NORA, HERDS, and nursing home survey data, to identify patterns, trends, areas of concerns, or non-compliance, and use this information as the basis for policy recommendations for infection control practices and for executing nursing home surveys as necessary;
   - Improve quality of publicly reported data;
   - Strengthen communication and coordination with localities on collection, reporting, and use of infection control-related data; and
   - Collect supplemental data through additional sources, such as the ICAR tool, and incorporate its use with current data sets.
2. Provide guidance to facilities on how to submit information into NORA and maintain support for data submitted on HERDS surveys to improve data quality, consistency, and accountability.
3. Develop and implement processes to improve controls over additions and deletions from CMS' database and determine if publicly reported nursing home survey data is reliable.
4. Evaluate and request resources as necessary to establish a foundation to adequately address public health emergencies in furtherance of the Department's mission.

To the Governor:

5. Assess and document the adequacy of the internal control environment at the Department and the Executive Chamber, and take necessary steps to ensure

29 CDC: Public Health Workforce Development Strategies

the control environment is adequate, including cooperation with authorized State oversight inquiries, communication with localities, and external reporting.

Audit Scope, Objectives, and Methodology

The objectives of our audit were to determine whether the Department is collecting necessary data to make informed decisions and promote strong infection prevention and control policies, and whether the data collected by the Department, including data reported to the public, is accurate and reliable. The audit covered the period from January 2017 through November 2021.

We experienced a number of delays obtaining information during the course of the audit. Recognizing that the Department was still dealing with a number of COVID-19 pandemic-related issues, we attempted to work with the Department to set a reasonable pace for receiving audit information. Although we engaged the audit in September 2020, we did not receive an initial meeting with officials until November 2020. We submitted an initial data request on November 18, 2020 for three items. We did not receive a completed response until December 29, 2020. As the audit progressed, the delays continued despite communication with officials that we needed to receive items timelier; requests continued to be outstanding for over a month. Also, although it further slowed the audit's progress, to ease the Department's workload and assist in scheduling meetings, we agreed to set meetings with Department officials every 2 weeks. However, we generally met only with higher-level officials, and had limited contact with program staff. Further, although we had scheduled meetings and provided topic agendas beforehand, we frequently did not receive answers to questions at these meetings; rather, officials asked us to submit our questions in writing afterward, to be answered at a later date.

We requested supporting documentation related to the Department's surveys of nursing homes, but never received it. In response, we were told that this data belongs to CMS and that the Department cannot release it to us without CMS' permission. Also, although requested, we were not provided documentation of correspondence from CMS explicitly denying our request for the information. The Department instead referred us to the publicly available data for nursing home surveys, which lacked sufficient detail to perform necessary testing.

To accomplish our objectives, we became familiar with and assessed the adequacy of internal controls as they related to our audit objectives. We interviewed officials from the Department to obtain an understanding of the processes for the systems used for infection control. We also interviewed officials from other states, specifically Washington and North Carolina, to discuss their best practices for dealing with the COVID-19 pandemic. We also received information from local county officials regarding communication with the Department during the pandemic. We reviewed applicable sections of State and federal regulations and standards, the SOM, and the Department's relevant policies and procedures.

We assessed the reliability of the HERDS, NORA, and nursing home survey data. For HERDS, we randomly selected 50 facilities using the 13,919 instances in which a COVID-19 death was reported between April 17, 2020 and May 23, 2021. We judgmentally selected three dates based on the dates when the Department changed its reporting of COVID-19 deaths publicly, and randomly selected a fourth date based on the remaining dates for which we had HERDS data (April 19, 2020 through May 23, 2021). We requested supporting documentation for 24 of the 86

fields in the HERDS data from the 50 facilities selected for each of these four dates and compared this documentation to the numbers reported in HERDS. For the 33 facilities that provided documentation we could test, the documentation generally supported the information submitted on the HERDS survey. However, because officials at 17 of the 50 (34%) facilities maintained little to no documentation, as well as our testing revealing an issue with the possible failure to report a death that raised questions about completeness, we were unable to determine the reliability of the data.

For NORA, we received a listing of all reports submitted to the Department with a reported date from January 1, 2017 through December 15, 2020, which totaled 7,757 reports. We analyzed the NORA data for missing or illogical dates and case numbers, as well as compared the COVID-19 cases reported against those reported by CMS over the same time frame, and found enough discrepancies to determine the data was unreliable.

For the nursing home survey data, we were unable to obtain the supporting documentation from the Department. However, we randomly selected 50 surveys between September 1, 2017 through August 10, 2021 that had at least one infection control deficiency cited from the Open Data public website, which resulted in a population of 722 surveys. We compared the fields from these 50 surveys (such as severity, residents affected, and correction date) to the data contained on the Department's own nursing home profiles website and found discrepancies for two of the 50 surveys. We also performed limiting testing on the general and application controls over the database used to store survey information, such as discussing the controls with knowledgeable officials. Between the limited testing we were able to perform and the lack of supporting documentation from the Department, we were unable to determine the reliability of the data.

To assess the number of infection control citations issued prior to the COVID-19 pandemic, we reviewed the number of citations issued and nursing home surveys performed between September 1, 2017 and February 28, 2020 from the Department's publicly available data for a population of 1,801 surveys with 11,595 citations. To assess whether any infection control issues appeared more frequently, we used the survey data available from CMS' website. Between February 8, 2016 and September 23, 2021, there was a total of 768 infection control citations. We identified key words, such as "PPE," "linen," and "legionella," and found the number of citations where each key word occurred within the inspection text.

To determine whether there was any correlation between facilities with flu outbreaks and COVID-19 outbreaks, we found the number of instances and cases of each reported by facilities in NORA between January 1, 2017 and December 15, 2020. We ran a correlation formula, which produced a correlation coefficient of 0.61, indicating a moderately strong positive correlation (on a scale of -1 to 1, with -1 being a strong negative relation, 0 being no relation, and 1 being a strong positive relation).

To assess whether the Department is conducting Health Safety surveys timely, we used a listing of all Heath Safety surveys conducted by the Department between

January 1, 2017 through July 9, 2021 for a population of 1,607 surveys. Due to COVID-19 and the suspension of certain nursing home surveys from CMS, we only considered surveys up until March 4, 2020, resulting in 1,450 surveys. We then compared the number of months between surveys for each facility, and found 396 instances in which the gap was greater than 16 months conservatively since the requirement is 15 months. To determine how many deficiencies were found during Infection Control surveys, we found all Infection Control surveys conducted and citations issued on the Open Data website, resulting in 602 citations between June 8, 2020 through August 16, 2021. Using this same data, we found the number of citations that had a correction date listed, which resulted in 189 instances.

The results of the samples we selected cannot be projected to the population as a whole.

Statutory Requirements

Authority

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.

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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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. These duties could be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our professional judgment, these duties do not affect our ability to conduct this independent performance audit of the Department of Health's oversight and administration of the use, collection, and reporting of infection control data.

Reporting Requirements

A draft copy of the report was provided to Department officials for their review and comment. Their comments were considered in preparing this final report and are attached in their entirety at the end of it. In general, officials agreed with our recommendations but took exception to certain statements in the report. Our responses to certain remarks are embedded within the Department's response as State Comptroller's Comments.

Within 180 days after final release of this report, as required by Section 170 of the Executive Law, the Commissioner of the Department 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.

Exhibit A

Policy Timeline

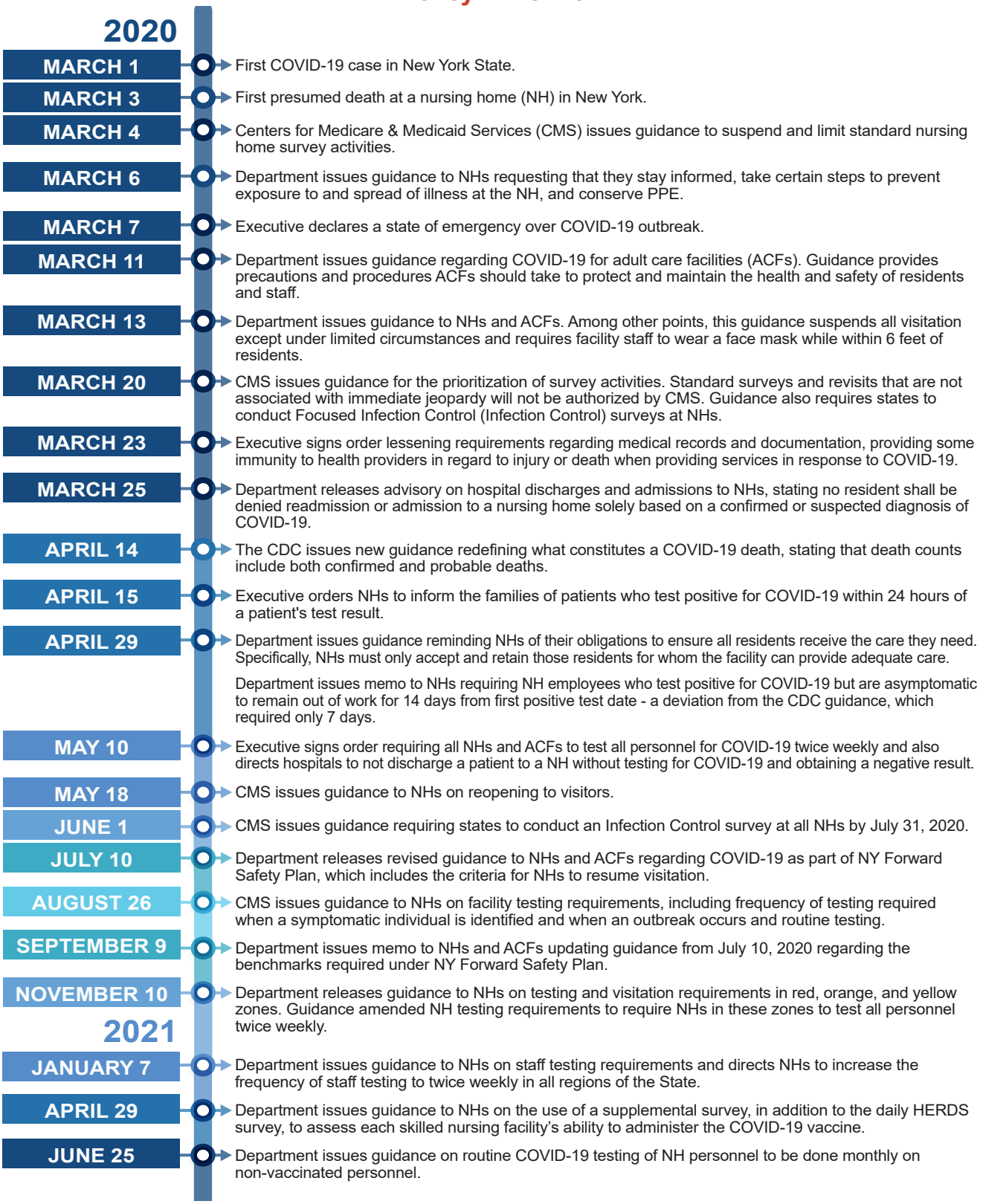

Exhibit B

Sources of Infection Control Data

System	Use
NORA	Facilities submit reports to the Department for most health care-associated infection outbreaks.
HERDS	Generates situation-specific surveys for facilities to complete and return; most extensively used to collect information on COVID-19 pandemic-related issues.
Nursing Home Surveys	
Standard Health	Encompasses Standard Health (quality of care) and Life Safety Code (fire and safety) recertification surveys, which must be performed at all nursing homes at least every 15 months.
Complaint	Conducted in response to complaints and incidents reported by either the nursing homes or third parties; only initiated if there is a complaint that needs to be investigated.
Infection Control	Started during the COVID-19 pandemic; used for a streamlined review of infection control activities at nursing homes.

Exhibit C

CMS' Deficiency Scope and Severity Grid

Severity	Scope		
	Level 1: Isolated	**Level 2: Pattern**	**Level 3: Widespread**
Level 4: Immediate Jeopardy	J*	K*	L*
Level 3: Actual Harm	G	H*	I*
Level 2: Potential for Greater Than Minimal Harm	D	E	F*
Level 1: Potential for No More Than Minimal Harm	A	B	C

*Substandard Quality of Care – Refers to Scope/Severity Levels F, H, I, J-L in one of the following Regulatory Groups: Resident Behavior & Facility Practices (42 CFR 488.13); Quality of Life (42 CFR 483.15); or Quality of Care (42 CFR 488.25).

Severity Levels (1–4)

- **Level 1** – Deficiency with potential for no more than minor negative impact on resident.
- **Level 2** – Non-compliance with no more than minimal physical, mental, and/or psychosocial discomfort to resident and/or has potential (not yet realized) to compromise resident's ability to maintain and/or reach his/her highest practicable physical, mental, and/or psychosocial well-being as defined by resident assessment, plan of care, and provision of services.
- **Level 3** – Non-compliance resulting in negative outcome that compromised resident's ability to maintain and/or reach his/her highest practicable physical, mental, and/or psychosocial well-being defined by resident assessment, plan of care, and provision of services. Does not include a deficient practice that only could or has caused limited consequences to resident.
- **Level 4** – Immediate jeopardy, where immediate corrective action is necessary because facility's non-compliance with one or more requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in the facility.

Scope Levels (1–3)

- **Level 1** – One or a very limited number of residents affected, staff involved, and/or situation only occasionally or in very limited number of locations.
- **Level 2** – More than a very limited number of residents affected, staff involved, and/or situation occurred in several locations, and/or repeated deficient occurrences to same resident but not pervasive throughout facility.
- **Level 3** – Problems causing deficiencies are pervasive in facility and/or represent systemic failure that affected or has potential to affect a large portion or all facility residents.

State of New York
Executive Chamber
Albany 12224

Kathy Hochul
GOVERNOR

Kathryn Garcia
Director of State Operations and Infrastructure

February 8, 2022

Thomas P. DiNapoli
Office of the State Comptroller
110 State Street
Albany, NY 12236

Re: OSC Draft Audit Report 2020-S-55

Dear Comptroller DiNapoli,

The Executive Chamber welcomes the opportunity to comment on the above-referenced Office of the State ("OSC") Comptroller Draft Audit Report of the New York State Department of Health ("DOH"). We understand that OSC raised concerns about the adequacy of the internal control environment under the prior administration, including cooperation and communication with authorized State oversight inquiries and localities, and other external reporting. We want to assure the OSC that upon taking office, Governor Kathy Hochul directed her administration to dramatically change course and prioritize transparency, including cooperation and communication with oversight agencies on all levels. To this end, Governor Hochul directed each executive agency and public authority to create transparency plans, announced steps to expedite the Freedom of Information Law process, implemented recusal policies at the Executive Chamber, and proposed the formulation of an independent commission on ethics and lobbying. In addition, under her new leadership, DOH and the Executive Chamber will continue to work together to ensure the highest standards of internal controls.

Sincerely,

Kathryn Garcia
Director of State Operations

NEW YORK STATE OF OPPORTUNITY. Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

February 9, 2022

Ms. Nadine Morrell
Office of the State Comptroller
Division of State Government Accountability
110 State Street – 11th Floor
Albany, NY 12236-0001

Dear Ms. Morrell:

Enclosed are the Department of Health's comments on the Office of the State Comptroller's Draft Audit Report 2020-S-55 entitled, "Department of Health - Use, Collection, and Reporting of Infection Control Data."

Thank you for the opportunity to comment.

Sincerely,

Kristin M. Proud

Kristin M. Proud
Acting Executive Deputy Commissioner

Enclosure

cc: Diane Christensen
Melissa Fiore
Ursula Bauer
Johanne Morne
Emily Lutterloh
Mark Hennessey
Valerie Deetz
Mary Jane Vogel
Sheila McGarvey
Ernest Clement
Jennifer Treacy

Empire State Plaza, Corning Tower, Albany, NY 12237 | health.ny.gov

Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2020-S-55 entitled, "Department of Health Use, Collection and Reporting of Infection Control Data"

The following are comments by the New York State Department of Health (the "Department" or "NYSDOH") in response to Draft Audit Report 2020-S-55, entitled "*Department of Health – Use, Collection, and Reporting of Infection Control Data*" (the "Draft Report"), prepared by the Office of the New York State Comptroller's Division of State Government Accountability ("OSC"). The Department welcomes the opportunity to comment on the Draft Report and its draft conclusions. In particular, the Department appreciates the opportunity to clarify multiple areas in which the Draft Report appears to misapprehend the Department's significant Covid-19-related undertakings and relies on an incomplete set of relevant facts – including with regard to the available sources and uses of public health data during the course of Covid-19 pandemic. The Department respectfully requests that the general and specific responses below will be taken into consideration and incorporated into OSC's final report.

General Comments:

The Department appreciates the stated goal of OSC's audit, which the Draft Report indicates was intended to determine whether NYSDOH is collecting sufficient data to make accurate and informed public health decisions and to promote strong infection control policies. The Department also appreciates OSC's efforts to ensure that New York State's public health systems are as robust as they can be given the resources made available to the Department. However, in reaching its draft conclusions, including OSC's draft conclusions regarding New York State's public reporting of Covid-19 mortality data under the previous Cuomo Administration, the Draft Report does not take proper account of the various types of quantitative and qualitative information that Department personnel have used to assist in responding to the Covid-19 pandemic; the various practical trade-offs that exist between different types of infection and mortality data; or the affirmative efforts that Department personnel have made over the past several years to enhance both the scope and the reliability of the information collected from nursing homes and hospitals to meet the challenges faced in the ongoing pandemic.

The Department further disagrees with the Draft Report's conflation of transparency concerns that have been raised regarding the prior Administration's public disclosures of Covid-19 information and the Department's own development and use of public health data for epidemiological and infection control purposes. As the Draft Report acknowledges and the New York State Assembly concluded during its investigation concerning the State's public disclosures, the scope of health data that was released to the public by the prior Administration was determined by that Executive Chamber, not Department personnel, and any Department-

issued data was accurately described. Whatever criticisms may now be directed at the prior Administration relating to issues of transparency, or the particular categories of information that were publicly disclosed, those ultimately were matters for the Executive Chamber of the prior Administration and not Department personnel.[1] The Department's use and analysis of available data for public health purposes was not affected or constrained in any way by the prior administration's public reporting determinations, and included both nursing home and hospital-supplied information encompassing the full range of data collected from healthcare providers impacted by the pandemic.

State Comptroller's Comment – The findings in each section of the report are distinct with separate causation. Moreover, while problems existed with reliability and completeness, information being inaccurately described was not one of the issues identified related to the Department's development and use of public health data.

The Draft Report does not address the practical challenges that the Department, together with federal and other state health departments, encountered from the earliest days of the Covid-19 pandemic to gather time-sensitive and comprehensive infection, mortality, and personal protective equipment ("PPE") information that was not available using the traditional data collection methods historically used to monitor and combat infectious diseases or track mortality data. Nor does the Draft Report fairly address the significant and successful efforts that Department personnel have made to enhance and transform New York State's existing data collection regimes to meet those challenges. The Department was required to make pragmatic decisions to meet the need for daily, real-time information, and the Department moved quickly to repurpose and augment New York's existing systems to gather the information it needed from nursing homes and hospitals. In congruence with the stated purpose of OSC's draft audit report, the Department continually improved these systems over the course of the pandemic to gather new categories of information, to enhance its reliability and audit its results, and to conform New York's information-gathering practices to applicable regulatory standards.

While Department personnel updated and expanded the State's health data collection systems in March and April of 2020, it was only after the initial 2020 surge was already largely *over* in New York that the Centers for Medicare & Medicaid Services ("CMS") – the federal regulator responsible for overseeing nursing homes – first began to collect detailed Covid-19 infection and mortality data using the National Healthcare Safety Network ("NHSN"). Even then nursing homes still were not required to supply CMS with comprehensive retrospective information of the type that the Department has required.

As the Draft Report acknowledges, for the past two years, the Department's dedicated professionals have tirelessly responded to an unprecedented global pandemic. They did so under difficult conditions and with limited federal assistance. The Department also made the best use of the resources it had and steadily improved its systems throughout the pandemic.

[1] The Department notes that the current Administration moved swiftly to address these concerns by further expanding the scope and sources of public reporting data. The Department is unaware of any continuing disputes or criticism regarding the scope of New York State's current public reporting regime.

State Comptroller's Comment – As the report acknowledges, Department staff worked tirelessly throughout the pandemic. However, that does not negate our belief that better data and information systems prior to the pandemic would have provided them with more accurate and complete information early on to assist them in their work. Moreover, a more adaptable and scalable centralized information system would have more readily allowed the Department to quickly expand the State's data collection needs, collect accurate and complete information, and share data with relevant stakeholders.

The Draft Report does not explain how any alternate systems would have worked in practice; whether other alternate tools (including CDC's Infection Control Assessment and Response ("ICAR") tool, which the Draft Report references) could have been quickly deployed in New York or would have yielded more reliable information; how the Department could have done a better job addressing the significant information-gathering challenges that led the Department to embrace and enhance its existing systems; or how data from distinct systems relayed by different types of providers could be combined or compared given the different methods, means, and purposes for each collection mechanism.

State Comptroller's Comment – Our findings are based in part on research presented by the Department's own staff and local health departments prior to and during the pandemic as well as conversations with public health experts from across the country. By listening to the Department's own experts as well as those from other states who identified tools they found to be effective in assisting with their response to the pandemic, we believe that Department officials can answer these questions and identify best practices they can employ in the future.

More fundamentally, the Draft Report's implication that collecting data in a different manner prior to the pandemic's outbreak or publicly reporting that information differently during the pandemic could have altered the course of the pandemic in New York is simply not correct. The Department used all the information at its disposal to identify outbreaks, to arrange follow-up on-site facility visits to ensure compliance with regulatory requirements, and to determine whether particular nursing homes or hospitals were in need of additional PPE. New York was one of the first states to identify and plan for the Covid-19 threat, to make ambitious sourcing and funding decisions to independently acquire ventilators, PPE and other materials needed to respond to the pandemic, and to ramp up its own independent testing capacity when the federal government was telling states that they were on their own. Where the Department was not able to provide requested assistance, this was due to nationwide shortages in PPE and testing availability, not failings of the Department's infection control surveillance.

State Comptroller's Comment – The report does not state or imply "that collecting data in a different manner prior to the pandemic's outbreak or publicly reporting that information differently during the pandemic could have altered the course of the pandemic in New York." Rather, we state, on page 11 and throughout the report, that better analysis and data reliability efforts might have allowed the Department to more effectively use resources at its disposal for day-to-day operations and in response to public health emergencies. Further, we credit the Department in areas where it did successfully use its data, specifically on page 22 in regard to its efforts to track and provide PPE to facilities.

Finally, the Department respectfully disagrees with the Draft Report's suggestion that the Department did not fully cooperate with the OSC's Staff's audit. Responding to the ongoing

pandemic has imposed around-the-clock demands on the Department and its personnel for nearly two years. These demands continue to the present day as the result of the recent Delta and Omicron variants. At the outset of OSC's review, the Department requested that OSC defer its audit efforts until the Covid-19 crisis abated. OSC declined that request. The Department nonetheless met or spoke with OSC Staff on not less than seven separate occasions to answer OSC's questions. Given the broad range of questions asked by OSC, the Department also requested that the audit team forward detailed questions in writing so that the Department could compile consolidated responses to OSC's numerous information requests. This request was made to facilitate accurate and comprehensive responses, not to impede OSC's review. OSC resisted this request as well, requiring Department personnel to respond directly on an ad hoc basis. The result was a slower and less orderly audit process than either OSC or the Department would have preferred. However, any associated delays in that process were simply the result of an overstretched public health workforce that is still actively addressing the ongoing pandemic.

State Comptroller's Comment – Throughout the course of the audit, the audit team respected the work that the Department was performing – specifically by agreeing to limited meetings just once every 2 weeks to accommodate the Department's schedule. However, as noted on pages 12 and 35, the team encountered numerous delays that had less to do with an unavailability of staff and more to do with the Department's lack of willingness to share requested information. For instance, prior to each meeting, we provided officials with a summary of the topics to be discussed. However, Department management would invariably bring staff to the meeting who could not or would not answer questions or provide needed documentation in the identified subject areas of the meeting. This was not a good use of either Department staff's or auditors' time and resulted in further delays and extending the audit.

Recommendation #1:

Develop and implement policies, procedures, or processes to:

- Expand use of infection control data, including but not limited to NORA, HERDS, and nursing home survey data, to identify patterns, trends, areas of concerns, or non-compliance, and use this information as the basis for policy recommendations for infection control practices and for executing nursing home surveys as necessary;
- Improve quality of publicly reported data;
- Strengthen communication and coordination with localities on collection, reporting, and use of infection control-related data; and
- Collect supplemental data through additional sources, such as the ICAR tool, and incorporate its use with current data sets.

Response #1:

The Department agrees with OSC Staff that expanding and improving the data available to the Department for epidemiological and other public health purposes is a worthy goal. The

Department shares that goal, and the Department's public health professionals have worked throughout the Covid-19 pandemic to improve the Department's existing systems and meet the challenges created by the pandemic. These efforts have included substantial efforts with respect to the State's existing data collection tools, especially data collected using the State's Health Electronic Response Data System ("HERDS"). The Department likewise is open to exploring new and improved mechanisms for collecting data from nursing homes, hospitals, and other health care providers where authorized and appropriately funded under applicable law. The Department shares OSC's view that New York should always be looking for newer and better ways to inform its public health initiatives. The Department will also be taking the data-related lessons it has learned from the Covid-19 pandemic into account going forward. However, the Department respectfully disagrees with the Draft Report's conclusions in its entirety.

First, the Draft Report does not address the practical complexities associated with the various data sources available to the Department during the pandemic. The Department has collected several distinct categories of public health data during the course of the pandemic. For example, as the Draft Report indicates, throughout the course of the pandemic, infection, mortality, PPE, and other information has been gathered directly from hospitals, nursing homes, and adult care facilities using New York's HERDS system, which gives the State the ability to transmit daily information-gathering surveys directly to health care providers and institutions. Certain Covid-19-related information likewise has been collected via the Nosocomial Outbreak Reporting Application ("NORA") maintained on the State's Health Commerce System, as well as via facility surveys. At the same time, mortality-related information historically has been collected pursuant to New York's Electronic Death Registration System ("EDRS"), which is a longstanding death-reporting system that predates the pandemic and is commonly referred to in New York as "Vital Records."

State Comptroller's Comment – We recognize there are complexities in using various data sets and systems cooperatively. However, as noted on page 11 of the report, the Department does not routinely analyze the data broadly, nor does it take advantage of certain other data sources, to detect interfacility outbreaks, geographic trends, and emerging infectious diseases or to shape its infection control practices and policies and its oversight of facilities. This is contrary to its own guidance, which states that the reporting and collection of the data is important for these reasons. We again note on page 21 that the Department did not prioritize the use of its various data sets collectively to make decisions, despite the vast amounts of data available and despite prior audits by our office recommending that the Department do so. Had the Department addressed integrating these data sets prior to the pandemic, it would have had greater intelligence at its disposal during the pandemic.

Each of these systems has its distinct advantages and limitations, including key differences in data timing, collection, and formatting that makes aggregating or syncing data across different datasets problematic as a statistical matter. Each of these systems serves a different purpose, so each system has different sources, settings, and contents. Further, because overlapping HERDS information is gathered separately from both nursing homes and hospitals concerning the same patients, certain nursing home resident information can be duplicative of information supplied by hospitals for patients transferred from nursing homes.

Correspondingly, these available data sources have distinct uses and limitations. For example, the Department's Vital Records reporting historically has been based on EDRS, a well-established data collection and reporting system that is based on certified death records and the actual location (*e.g.*, hospital, nursing home, private residence) of the individual's death.[2] A certified death record is the legal record of death as submitted by a medical certifier (*i.e.*, medical examiner, coroner, physician) to the local registrar. However, for much of the initial phase of the pandemic, New York (along with other states) experienced significant system-wide delays in the local certification and reporting of deaths, as medical examiners and other local certifiers struggled to keep up with the volume of deaths and correctly identify deaths caused by Covid-19 as opposed to other comorbidities (a process that was made even more difficult during the initial phase of the pandemic by the general unavailability of testing). As such, for much of the initial 2020 "surge" in New York, EDRS (and parallel CDC) data based on death certificates simply could not provide the type of timely data that the Department needed to surveil and evaluate the pandemic's impact on hospitals or nursing homes.

To address this timing challenge, the Department quickly repurposed its HERDS data collection system at the outset of the pandemic to gather real-time infection, mortality, and other information from both nursing homes and hospitals. By contrast to EDRS and Vital Records data, the HERDS system was not established (or intended) in the first instance for comprehensive Vital Records collection or public reporting purposes. It was instead used for more limited information-gathering purposes, such as in connection with weather-related or other emergencies. However, given the pressing need to obtain information on cases and deaths as quickly as possible to surveil the real-time experiences of healthcare providers, starting in March 2020 the Department began using HERDS to gather Covid-19 information from hospitals, nursing homes, and adult care facilities using a flexible survey format. Because HERDS allowed DOH to issue daily surveys to those facilities, this gave NYSDOH access to a broader range of information than was being collected using EDRS or NORA. Because certified death records were also experiencing substantial delays, using HERDS to contact providers directly also offered much more timely death information for monitoring purposes than was otherwise available at the time.

As the Draft Report acknowledges, the Department's HERDS surveys evolved and became more elaborate over time, collecting information about disease burden, capacity, supplies, and resident fatalities. Department personnel routinely followed up directly with healthcare providers regarding the specific contents of their responses, to gather additional information, and to address and resolve any potential inaccuracies or inconsistencies identified during the course of DOH's review given that health care providers were self-reporting information on accelerated timelines without the benefit of the types of independent confirmation and patient-level detail associated with Vital Records.

[2] Given New York's longstanding (pre-pandemic) Vital Records practice of reporting deaths based on the actual location of the decedent's passing, the Department does not agree with the Draft Report's suggestion that disclosing HERDS data based on in-facility deaths at facilities is misleading in any respect. This is how Vital Records in New York have historically been reported. However, in line with current Administration policy, the Department currently posts both in-facility and out-of-facility mortality information for nursing home residents even though certain out-of-facility nursing home resident deaths are also reflected in hospital death statistics.

These efforts, together with various initiatives by the Department over the past few years to audit and further diligence the information being supplied by nursing homes, did result in periodic updates and refinements to the Department's statistics as facilities' information was checked and updated. This reflects the kind of improvement that OSC is recommending the Department should be undertaking. HERDS data has various practical limitations, including the limitation that it is based on self-reporting, second-hand information for out-of-facility outcomes, and does not contain sufficient personally identifying information to conclusively identify individual patients whose outcomes may be simultaneously reflected in both nursing home and hospital-supplied data. But in conjunction with other survey results, NORA data, and the other information available to the Department, this data gave the Department a useful window into nursing homes' real-time infection experience and a mechanism for Department staff to monitor facility resources and capacity.

Second, the Draft Report's conclusions relating to the Department's NORA reporting system do not fairly address either the purpose of that system or its effectiveness. The NORA system was never intended to function as a comprehensive, retrospective vital statistics system. It was instead intended to function as an epidemiological notification system designed to flag potential outbreaks at facilities for Department follow-up. Taken together with the HERDS and other survey data available to the Department, NORA has served that purpose throughout the course of the pandemic.

State Comptroller's Comment – We do not suggest that NORA was intended to function as a comprehensive vital statistics system. Rather, we agree with the Department that not only is NORA an epidemiological notification system designed to flag potential outbreaks at facilities for Department follow-up but that "timely and **complete** [emphasis added] reporting of communicable diseases is critical for NYSDOH response activities" (see footnote 24). Unfortunately, the audit found NORA data is neither complete nor reliable, and Department officials, despite identifying this problem prior to the pandemic, did not follow through on the corrective actions they themselves suggested. This limited the usefulness of the data.

Further, the Draft Report states that OSC cannot conclude whether NORA data is complete or omits certain information. It also criticizes NORA data for not matching certain other patient-level information separately retrieved from CMS. However, NORA data is merely surveillance information that reflects a snapshot of an outbreak at the time a report is filed by a facility, and is not intended to sync up with CMS's separate datasets or function as vital records statistics. Initial NORA report information is instead used by the State's regional epidemiologists to prioritize their own direct outreach to facilities. When a facility submits a NORA report, an automated email is sent to the Department's Central Office staff, all epidemiology staff in the facility's region, and facility infection prevention staff. Regional regulatory staff and local health departments also have access to NORA reports for their respective jurisdictions. Many facilities will therefore receive outreach from a regional epidemiologist even before Central Office staff have triaged the report. This process ensures that facilities receive Department epidemiology outreach and support in a timely manner. Once an outbreak is over, regional epidemiologists do collect various historical data (including case counts) and enter that information into NORA to "close" the investigation. However, because

the principal purpose is to respond to the outbreak in the first instance, responding to outbreak reports, not retrospective data reporting, is the purpose of this system.

The Draft Report criticizes various NORA-related statistics and emphasizes that certain facilities previously had not reported information to the Department through NORA for a period of time. However, the Draft Report elsewhere concedes that these outliers previously were identified and remediated by the Department itself, which addressed that oversight directly as part of a grant-funded project. Notably, during the administration of that project, the Department's epidemiology team proactively searched for facilities that might benefit from targeted supplemental training and education about New York State's reporting requirements. Department epidemiologists continue to reach out to facilities in their regions to provide NORA-related training.

Additionally, the Draft Report places significant emphasis on typographical and clerical errors concerning a small number of NORA reports. However, the errors cited comprised only 125 (0.15%) of the 7,757 overall reports, all of which had already been addressed by an epidemiologist at the time of the report. Nor does the NORA system's reporting of near-duplicate reports reflect "unreliable" or "inaccurate" results. Out of epidemiologic and scientific necessity, each facility initially determines what constitutes an outbreak in its facility. Facilities also sometimes enter multiple reports that could be misinterpreted as duplicates. However, these decisions are often made in collaboration with Department epidemiologists and reflect the facility's conclusion that the cases being reported have no epidemiological link to each other and constitute separate outbreaks within the same facility. If and when an epidemiologist decides that duplicate reports have been filed those duplicates are purged from NORA.

State Comptroller's Comment – The Department states that the report "places significant emphasis on typographical and clerical errors"; and points to one example cited in the report and calculates the error rate to be 0.15%. However, this is an example (i.e., illustrative) and thus, by definition, is not meant to be a complete listing of the numerous data reliability issues present within the data. A point demonstrated in the subsequent paragraph (page 29) offers a second example of why we concluded NORA to be unreliable: "there were 18,807 confirmed patient cases of COVID-19 in CMS' data, but only 4,939 such cases in NORA – a difference of 13,868 cases." The Department's self-described "epidemiological notification system designed to flag potential outbreaks at facilities for Department follow-up" potentially not including 13,868 reported COVID-19 cases is of far more concern than any typographical or clerical error.

Third, the Draft Report is incorrect in its conclusion that the Department "does not routinely analyze the data broadly to detect inter-facility outbreaks, geographic trends, and emerging infectious diseases or to shape its infection control practices and policies and its oversight of facilities." From the very outset of the pandemic, the Department has used HERDS data and other available information to monitor resident and staff infection rates; identify outbreaks; track levels of available PPE; ensure compliance with regulatory requirements; confirm that appropriate infection control measures are in place; and track vaccination status, among other things.[3] In addition to using NORA for its primary function as a notification

[3] The Department also disagrees with the Draft Report's use of the correlation coefficient statistic calculation to identify high-risk facilities for future outbreaks. The correlation coefficient is a statistic for assessing the linear relationship

system, the Department uses NORA data to provide situational awareness to stakeholders. All NORA reports are addressed directly with each facility by an epidemiologist, including all 7757 reports that were identified during the audit period.

State Comptroller's Comment – The efforts the Department describes demonstrate that it uses its data largely as a notification and inventory system, not for analysis. The Department does not use its data for trend analysis, predictive analysis, or other more advanced functions that could be used for broader decision-making purposes. Further, as noted in our previous comments, we credit the Department in areas where it did successfully use its data, specifically its efforts to track and provide PPE to facilities.

Similarly, the Department has used the results of facility surveys to respond to the pandemic. The Department used data received from HERDS surveys to help determine where to perform focus infection control surveys ("FICS"). To date, the Department has completed 2,934 FICSs since March 2020. These surveys have proven to be a useful tool to ensure that nursing homes comply with state and federal infection prevention and control requirements. In addition, the Department updated its survey tool in May 2020 to ensure compliance with additional reporting and public health emergency requirements. The Department's adult care facility ("ACF") program also uses an infection control survey tool tailored to ACFs' unique non-clinical setting, which was developed in partnership with the Division of Epidemiology. In addition, based in part on its own surveillance efforts, each year the Department issues thousands of citations for issues relating to the provision of health care and life safety noncompliance. Over the course of the pandemic, in addition to conducting more than 2900 FICSs, the Department responded to extensive provider inquiries, assisted with facility education and guidance, and generated over 1,700 enforcement referrals relating to nursing home non-compliance in the areas of infection control and prevention, PPE non-compliance, and state licensure requirements.

State Comptroller's Comment – As noted on page 9, the efforts regarding focused infection control surveys (FICSs) were generally directed by CMS, including any updates. Further, as we state on page 26, the Department was slow to begin cconducting FICSs until CMS required they be completed by July 31, 2020. In fact, as noted in our report again on page 26, according to the U.S. Department of Health and Human Services Office of Inspector General's report, the Department had surveyed only 3% of nursing homes in the first month following CMS' directive, and by May 30 had only performed Infection Control and Complaint – immediate jeopardy surveys for 20% of nursing homes between March 23 and May 30, 2020, compared with over 90% for other states. Finally, adult care facilities were generally outside the scope of this audit as our focus was largely on nursing homes.

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between two variables. It is a global summary measure of the linear relationship between two continuous variables in a data set. Infectious disease outbreaks, however, are complex and involve numerous factors, and the relationships may be quite nonlinear, rendering the use of the correlation coefficient questionable, simplistic, and unreliable. The Department, instead, relies on more sophisticated statistical approaches to detect potential outbreaks, including multivariate regression models that can address the complex relationships across multiple variables.

State Comptroller's Comment – The Department misunderstands the system we used to calculate the correlation coefficient statistic. The Department incorrectly assumed that the calculation was done using both HERDS and NORA. As we state on page 23, our calculation was based on one system: NORA. Further, the Department states that it performs analysis on the data; however, despite our repeated requests, the Department did not provide us with any documentation of such analysis, as stated on page 23.

The Department's efforts in this regard were also accompanied by various other targeted actions focused on facility training, regulation, and surveillance, all of which were informed by the information being gathered in real time by the department. For example, among other things, during the course of the ongoing pandemic, the Department:

- Issued multiple guidance documents, including the Covid-19 Preparedness Self-Assessment Checklist, which also functioned as an investigative tool during facility investigations by the Department. The Checklist provided nursing homes with guidance regarding the infection prevention and control elements that needed to be in place before and after recognition of confirmed or suspected cases of Covid-19;

- Provided targeted assessments and guidance by the Department's epidemiology team to strengthen infection prevention and control practices and provide mitigation recommendations. This included direct phone outreach by Department epidemiologists to all nursing homes in the early weeks of the pandemic to ensure that facilities were aware of the infection prevention and control measures that could be implemented;

  State Comptroller's Comment – While the efforts listed in the bullets are commendable, they largely fall outside the scope of this audit, which focuses on the utilization and reporting of the Department's data.

- Worked in collaboration with CDC from March 7, 2020 through April 20, 2020 to conduct multiple nursing home investigations, provide guidance, and conduct on-site visits, which resulted in CDC feedback that the Department had implemented all recommended infection control strategies;

- Moved swiftly after New York's first reported Covid-19 case to require face masks and health screenings, as of March 13, 2020, for nursing home staff and focus the Department's surveillance activities on Covid-19;

- Launched innovative video conferences using smart phones ("COVID-eos") to augment on-site epidemiology infection control visits;

- Developed and maintained a dedicated bureau mail log ("BML") system to respond 7 days a week to Covid-19-related questions by providers;

- Made daily calls to facilities reporting high transmission rates of Covid-19, as well as facilities with data inconsistencies, as part of our ongoing response and quality control efforts to strengthen facilities' infection prevention and control strategies and to improve the quality and integrity of self-reported nursing home data;

- Managed facility capacity using the Department's Nursing Home Assistance Call Center; and

- Used HERDS data to develop PPE recommendations and allocate in-demand PPE to facilities across the state.

In sum, the Department used available data sources to inform its overall Covid-19 response. Infection, mortality, and PPE data have been used daily for the past several years to inform virtually every aspect of the Department's activities. The Department will continue to use these data sources for this purpose and will look for other opportunities to enhance its sources of available data.[4]

Fourth, it is not proper to conflate the prior Administration's separate public reporting determinations with the Department's own use and analysis of available Covid-19 data. As the Draft Report concedes, decisions regarding the scope of public reporting were made by the prior administration, not the Department. Nor did those prior administration decisions impact the Department's own epidemiological use of data collected by the Department – including both nursing home self-reported data and information collected directly from hospitals at which nursing home residents were hospitalized.

State Comptroller's Comment – Our report makes no such assertions. In fact, our report made a concerted effort to separate how the Department used data throughout the pandemic and how the death data was reported.

Further, while the Draft Report criticizes the prior Administration for a lack of transparency in not disclosing more information, none of the reports that were made to the public under the Department's purview were false or inaccurate, as the Draft Report now implies. Instead, all reports issued by the Department plainly identified the data sources they included and were accurate, a fact that the New York State Assembly's investigative report has acknowledged.

State Comptroller's Comment – As noted on page 13, we found that the reports of deaths were inaccurate for the period April 15 to May 2, 2020. This was not a matter of disclosure or transparency, but an inaccuracy in the data as reported and as supported by the Department's own data compared to what was reported to the public at that time. Further, when asked, Department officials admitted they could not explain the reason for the inaccuracy.

In any event, with the direction and strong support of the current Hochul Administration, the Department has undertaken new initiatives to make more data available so that the legislature, agency stakeholders, and the public may better understand the State's pandemic response. A new Department website incorporates a single landing page for Covid-19 dashboards that is easy to access[5], rather than having to navigate different dashboards on different platforms. In addition, the Department has retooled several dashboards to provide information in a manner that is easier to understand and more relevant to current needs. Health Data NY also now includes additional self-reported data from the Covid-19 School Report Card, nursing home and adult care facility fatality data, and hospital admissions by gender and zip

[4] The Draft Report recommends that the Department collect supplemental data through additional sources, such as CDC's ICAR tool. CDC updated its ICAR tool on January 7, 2022, but only 14% of all states have acknowledged their use of that tool. Regardless, the Department's epidemiologists will review the new version of that tool and consider it in conjunction with the tools that epidemiologists have adapted to their individual needs and the needs of the nursing homes they serve, including but not limited to the Department's own COVID-19 checklist.

[5] https://coronavirus.health.ny.gov/covid-19-data-new-york

code, as well as hospital capacity and staff vaccination numbers. Under Governor Hochul's leadership and the oversight of the Department's Commissioner, Dr. Mary Bassett, these efforts have been widely praised and the Department expects them to continue going forward.

Recommendation #2:

Provide guidance to facilities on how to submit information into NORA and maintain support for data submitted on HERDS surveys to improve data quality, consistency, and accountability.

Response #2:

The Department has conducted extensive trainings with nursing homes and their associations regarding completion of the daily HERDS surveys. Extensive instructions were incorporated into the survey itself, and the Department has routinely provided direct input and guidance during daily quality control calls and in response to inquiries made via the Department's dedicated BML.

Similarly, regarding the NORA system, regional epidemiologists have provided and continue to provide ongoing education, as needed, regarding the technical aspects of submitting a NORA report and when reporting is warranted. The need for such assistance depends on the experience and expertise of facility personnel. Additionally, the Department has taken steps to ensure that NORA reports are appropriately triaged. This includes no longer "holding" reports while epidemiologists research to determine if the reports are warranted (typically in cases where multiple reports are submitted by the same facility within a short timeframe). Epidemiologists triaging NORA reports now operate under the assumption that every report is justified and all reports are triaged and submitted. If a report is later deemed to be in error or duplicative, it is purged from NORA. This requires an additional staffing commitment but improves triage data reliability. Triage staff also have been instructed to use the NORA software's calendar function, rather than manually entering dates, to improve accuracy and reduce human errors in recording dates. Regional epidemiology staff will also continue to provide NORA training on an individual basis to any nursing home requiring assistance.

In addition to these efforts, the Department enhanced its FICS survey process in May 2020 to include onsite review of critical data elements, including nursing home fatalities and compliance with state requirements and Executive Orders, as an additional means to assess compliance and validate the information submitted through HERDS. During onsite reviews, observations, record reviews, and interviews were conducted with nursing home personnel and others to verify not only death reporting, but also the various metrics associated with the Department's HERDS data collection (case counts, lab results, etc.). Data validation has continued to be a top focus for the Department. Although patient-level data is not encompassed within each of the available HERDS fields, the Department's data collection efforts and personal follow-up by Department call center personnel has enhanced the reliability of HERDS data over the course of the pandemic.

Recommendation #3:

Develop and implement processes to improve controls over additions and deletions from CMS' database and determine if publicly reported nursing home survey data is reliable.

Response #3:

On November 5, 2021, the Department supplied OSC's audit team with an explanation and response regarding their stated concerns regarding their October 28, 2021 inquiry concerning differences between publicly reported survey data reported in CMS data and NYS Nursing Home Profile Data. As the Department noted in that response, there are different types of citations: those cited for violations of only a state regulation and those cited for violations of only a federal regulation. In some cases, the Department may issue citations for violations of both state and federal regulations. However, there are certain federal citations that may only be levied by CMS. A review and reconciliation of data maintained in the federal CMS survey database was conducted in April and May 2018, and again in January and February 2020. The Department reviewed the discrepancies identified by OSC Staff between CMS and NYS Nursing Home Profile Data. As noted above, CMS only posts federal citations, not state-only citations. This is the reason for three of the discrepancies identified by OSC. The remaining discrepancies concern citations involving federal regulations that were wholly subject to CMS' purview.

State Comptroller's Comment – The correspondence from the Department did not explain the reasons for the discrepancies; rather, the Department responded that it was unable to explain why certain citations were not in CMS' data.

Recommendation #4:

Evaluate and request resources as necessary to establish a foundation to adequately address public health emergencies in furtherance of the Department's mission.

Response #4:

The Department shares OSC's stated goal of requesting and evaluating further resources, and will continue to do so going forward. The Department looks forward to working with all stakeholders to secure the appropriate resources to attract, train, and fund the necessary epidemiologists, infection preventionists, and public health specialists to carry out the Department's public health responsibilities. The Department has a renewed sense of purpose and optimism from the new Administration and Health Commissioner, and is committed to rebuilding its resources to support a strong and diverse public health workforce.

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