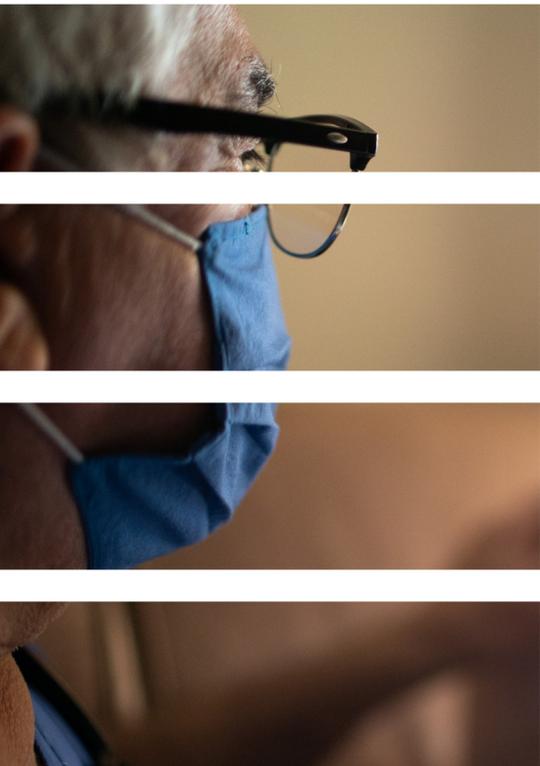




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## Preparing for Pandemic-Related Audit and Investigation

On the front lines of the COVID-19 fight, nursing homes and elder care facilities are facing heightened scrutiny from federal and state agencies. Nixon Peabody attorneys are guiding clients through this evolving regulatory landscape. As part of that effort, we have created a checklist of steps that facilities should consider taking today, if they have not already, to prepare for success in the event of a government audit, investigation, enforcement action, or lawsuit.

No compliance program is one size fits all, and each facility should adopt and tailor compliance measures to their specific operations. This checklist—drawn from past guidance on effective compliance programs, and the latest pandemic response requirements and recommendations—includes measures that are recommended by government authorities in a broad range of circumstances.



# A compliance checklist for nursing homes and elder care facilities:

## ✓ **Appoint a pandemic compliance monitor or committee**

These individuals should have sufficient seniority and authority to demonstrate the organization's commitment to compliance during the pandemic. They should have direct access to management and the board, but should not be subordinate to either. The compliance monitor or committee should be responsible for analyzing all federal and state guidance, taking immediate action to ensure compliance, and carefully documenting their actions.

## ✓ **Document resource shortages and all efforts to mitigate them**

Adequate equipment will help insure proper infection prevention and control. Taking robust, proactive steps to secure necessary testing, personal protective supplies, and durable medical equipment—and documenting these actions—lessens the chance that facilities will be blamed for equipment shortages, should they occur.

## ✓ **Suspend routine deletion of electronic communications related to pandemic response**

Even if a facility does not currently anticipate litigation concerning its pandemic response, management should preserve all records concerning that response. Federal and state regulations may require preservation of certain records for set periods.

## ✓ **Prepare written procedures that implement government mandates and guidance, and memorialize the interpretation**

Some regulatory language can be ambiguous. For example, the Centers for Medicare and Medicaid Services, has recently required facilities to report the contemporary onset of “respiratory

symptoms” among three or more employees or residents within 30 days. As CMS does not define “respiratory symptoms,” facilities should document their good-faith interpretation of “respiratory symptoms” and assure that staff consistently apply that understanding.

## ✓ **On an ongoing basis, train and educate staff on the latest pandemic-related requirements and the procedures implemented to comply with them**

CMS recommends that all staff receive at least annual training on an organization's compliance program and prompt, ongoing training on pandemic-related compliance measures.

## ✓ **Develop a system to ensure and document staff training and implementation of pandemic-related protocols**

This system may include an email confirmation or written certification that staff must complete after training. It should also include some assessment of employee comprehension of requirements, such as a short quiz or other form of internal audit by management.

## ✓ **Designate an individual responsible for promptly communicating with public health authorities, residents, and family members about confirmed or suspected COVID-19 cases**

Failure to report, or underreporting, may be grounds for deficiency citations and civil monetary penalties, and lead to protracted government enforcement actions. Some states, like New York, have threatened immediate action against licenses. To mitigate those risks, facilities should be prepared to show through contemporaneous documentation that they made reasonable efforts to contain the spread of infection and keep stakeholders informed.



✓ **Monitor published data on reported COVID-19 infections and deaths among nursing homes and adult care facilities to assess how a facility compares to others in the state and local area**

Federal and state authorities are publicly reporting infection-related data for specific nursing facilities. Although this information does not tell the full story of how a facility has managed the crisis, government enforcement agencies are likely to monitor this data to identify outliers for possible investigations. A good practice is to take steps to know where they stand among peers and identify any seemingly disproportionate rates of infection or death.

✓ **Encourage internal reporting of concerns and protect those who report**

CMS generally recommends that as part of their compliance programs, federal health care providers develop a confidential reporting system. Management should encourage staff and residents to report any concerns and assure them that reporting will not result in adverse action.

✓ **Have a plan for responding quickly and effectively to requests from the government, including for audit, inspection, documents, or other information**

Facilities should be ready to provide timely and complete responses to inquiries by federal or state government agencies. If an organization is contacted by a government agent, it is prudent to involve counsel immediately.

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## Our team

NP's Government Investigations & White Collar Defense group, *which includes 11 former federal prosecutors*, defends companies and individuals against liability in investigations and litigation. Our firm, which also includes *numerous former state assistant attorneys general*, helps clients develop strategic compliance measures to avoid exposure, including assessing mandated reporting requirements, developing written policies and protocols, and drafting reports to constituencies.

Recently, we've worked with:

- A national hospital chain in connection with the federal investigation of the New England Compounding Center and the multistate outbreak of fungal meningitis.
- A hospital as coordinating counsel in the criminal, regulatory, and civil actions arising from the infection of patients with Hepatitis-C, allegedly by a former employee.
- The owner of multiple skilled nursing facilities in a federal investigation involving Medicare billing issues.
- A nursing home management company with numerous skilled nursing facilities in a False Claims Act investigation conducted by the U.S. Attorney's Office in Massachusetts, and related qui tam case.
- A national hospice company in an ongoing DOJ probe of a qui tam action.



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FOR MORE INFORMATION,  
PLEASE CONTACT:



Hannah Bornstein  
617-345-1217  
[hbornstein@nixonpeabody.com](mailto:hbornstein@nixonpeabody.com)



Brian K. French  
617-345-1258  
[bfrench@nixonpeabody.com](mailto:bfrench@nixonpeabody.com)



Peter Millock  
518-427-2651  
[pmillock@nixonpeabody.com](mailto:pmillock@nixonpeabody.com)



Tina Sciocchetti  
518-427-2677  
[tsciocchetti@nixonpeabody.com](mailto:tsciocchetti@nixonpeabody.com)



Adam R. Tarosky  
202-585-8036  
[atarosky@nixonpeabody.com](mailto:atarosky@nixonpeabody.com)

NIXONPEABODY.COM  
@NIXONPEABODYLLP