
Health Law Daily Wrap Up

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Compliance requirements for providers may be evolving as rapidly as the response to the coronavirus itself, so it’s important for providers to prioritize protecting patients’ health and data, and their employees.

The novel coronavirus disease 2019 (COVID-19) has created many new challenges for facilities working to treat the surge in patients while trying to navigate the ever-changing compliance landscape. As more information becomes available about COVID-19 and how it is spreading, agencies continue to update their guidance for providers to help them overcome the challenges in treating patients, containing the spread of the virus, and protecting patient confidentiality. With the COVID-19 outbreak being a fluid situation that seems to change by the minute, the guidance from agencies is coming at record speed and making it difficult to keep up. This Strategic Perspective discusses the major compliance issues providers need to mindful of while they handle this outbreak.

Protecting Patient Health Information

As the COVID-19 outbreak continues to spread rapidly, sharing information with the Centers for Disease Control and Prevention (CDC) as well as state and local health departments may be important to help track where the infection is spreading and how quickly. Facilities need to be mindful of what information they disclose and to whom because the Health Insurance Portability and Insurance Act (HIPAA) still applies, even in a public health emergency like the COVID-19 outbreak.

HIPAA. The HHS Office of Civil Rights (OCR) issued a bulletin to ensure that HIPAA covered entities are aware of the ways that patient information may be shared under the HIPAA Privacy Rule in an outbreak of infectious disease or other emergency situations. HIPAA permits covered entities to disclose needed protected health information to a public health authority, such as the CDC or a state or local health department, without individual authorization. The covered entity may also disclose needed protected health information to persons at risk of contracting or spreading a disease or condition if other law authorized the entity to notify such persons as necessary to prevent or control the spread of the disease. Additionally, health care providers may share patient information with anyone necessary to prevent or lessen a serious imminent threat to the health and safety of a person or the public, consistent with applicable law. Reasonable efforts must be made to limit the information disclosed to that which is the “minimum necessary” to accomplish the purpose, and covered entities must continue to implement reasonable safeguards to protect patient information against intentional or unintentional impermissible use and disclosures.

Public health emergency waiver. HIPAA is not suspended during a public health emergency; however, HHS may waive certain provisions of HIPAA under the Project Bioshield Act of 2004 (P.L. 108-276) and section 1135(b)(7) of the Social Security Act. HHS opted to exercise this authority to waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:

- obtaining a patient’s agreement to speak with family members or friends involved in the patient’s care;
- honoring a request to opt out of the facility directory;
- distributing a notice of privacy practices;
- the patient’s right to request privacy restrictions; or
- the patient’s right to request confidential communications.
This waiver only applies in the emergency area identified in the public health emergency declaration, to hospitals that have instituted a disaster protocol, and for up to 72 hours from the time the hospital implements its disaster protocol. The waiver became effective on March 15, 2020.

**Telehealth waiver.** With the expansion of telehealth benefits to Medicare beneficiaries, the OCR announced that it would exercise its enforcement discretion and would not impose penalties for noncompliance with the regulatory requirements under the HIPAA rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. In order to encourage more providers to quickly transition to using audio or video communication technology to provide telehealth to patients during the COVID-19 outbreak, providers will be allowed to use any non-public facing remote communication product that is available to communicate with patients. This applies to telehealth provided for any reason, regardless of whether the telehealth services is related to the diagnosis and treatment of health conditions related to COVID-19. This will allow providers to examine a patient using audio or video communication technology to assess a greater number of patients while limiting the risk of exposure to other patients and thereby limiting the risk of infection.

**Protecting Patients from Exposure**

Evidence shows that COVID-19 can spread quickly through a health care facility, where there tends to be a large number of high-risk individuals. It's important for providers to take active measures to reduce the risk of patient exposure to COVID-19, such as screening patients and visitors before they enter the facility, reducing the number of non-essential staff and vendors, and taking general infection control precautions.

**Screening.** CMS recommends that hospitals screen patients and visitors immediately upon arrival to the health care facility to determine if they have a fever or symptoms of a respiratory infection, if they have traveled internationally within the last 14 days to restricted countries, or whether they have had contact with someone known or suspected of having COVID-19 (see CMS issues Coronavirus protection, prevention guidance for hospitals and nursing homes, March 5, 2020). Patients who are suspected of having COVID-19 should be separated from other patients waiting to be seen, and in some cases if patients are otherwise medically stable they may be allowed to wait outside or in their car and be notified via mobile phone when it is their turn to be evaluated.

Some hospital emergency room departments have run into issues with not having the space to isolate patients who arrive with suspected COVID-19 symptoms and those who do not. Under the Emergency Medical Treatment and Labor Act (EMTALA), emergency departments are still required to conduct appropriate medical screening examination of all individuals who come to the emergency department. For hospitals concerned about fulfilling their EMTALA screening obligations while minimizing the risk of exposure from COVID-19 infected individuals to others in the emergency department, CMS offered recommendations for alternative screening sites (see New coronavirus infection control guidance for facilities, home health providers, March 11, 2020). Alternative screening sites could include:

- another location on the hospital campus, such as outside the entrance to the emergency department or in another location completely;
- an off-campus screening site under the control of the hospital that the public may be encouraged to visit before visiting an emergency department; or
- an off-campus screening site set up by the community.

EMTALA requirements still apply to alternative screening sites that are under the control of the hospital. Also, although these alternative screening sites may be established, an emergency department may not redirect a patient who arrives at an emergency room to an off-site location for screening.

**Nursing homes.** According to the CDC, adults over the age of 65 are at higher risk for severe illness from COVID-19 and account for eight out of 10 deaths reported in the United States. Seniors with multiple health conditions are at the highest risk for complications, which makes nursing homes extremely susceptible to quick spread of the virus due to the large congregation of that particular vulnerable population. CMS has issued
guidance for infection control and prevention of COVID-19 in nursing homes and has continued to update and revise the guidance as more information becomes available (see Emergency declarations; more aggressive actions to control coronavirus, March 16, 2020). In an updated guidance issued on March 13, CMS encouraged nursing homes to take aggressive actions to reduce the risk of patient exposure, including:

- restricting visitation of all visitors and non-essential health care personnel, except for certain compassionate care situations;
- canceling all group activities and communal dining;
- actively screening residents for fever and respiratory symptoms;
- actively screening staff for fever and respiratory symptoms at the beginning of their shift and sending them home if they develop symptoms;
- providing personal protection equipment (PPE) to individuals allowed to enter the facility and advising them to monitor for signs and symptoms of respiratory infection for at least 14 days after exiting the facility; and
- taking steps to limit who enters the facility, such as asking vendors to drop deliveries outside at loading docks.

As the spread of COVID-19 continues to develop, different states may determine stricter requirements are necessary to protect residents. According to CMS, a state may impose stricter requirements through a governor’s order without being out of compliance with CMS requirements.

Home health care. Patients who are already receiving home health care services may not need to be transferred to a hospital if they develop COVID-19. Patients with mild symptoms may be managed at home if they can adhere to isolation recommendations. According to CMS, health care providers entering the home to provide care to the patient should take special care (see New coronavirus infection control guidance for facilities, home health providers, March 11, 2020). The number of health care providers entering the home should be limited to essential personnel only. Health care providers entering the home to provide care should wear all recommended PPE, which should be put on before entering the home. Any supplies brought into, used, and removed from the home must be cleaned and disinfected. When leaving the home, the health care provider should wait until he or she is outside of the home to remove PPE if possible and dispose of the PPE in an outside trash can.

Nonessential services. Many hospitals are feeling the strain of resources due to the rapidly increasing number of patients being treated for COVID-19. According to CMS, the conservation of critical resources such as ventilators and PPE is essential, as is limiting exposure of patients and staff to COVID-19. To that end, CMS has recommended that all non-essential medical, surgical, and dental procedures be delayed during the COVID-19 outbreak. The decision to halt these procedures remains the responsibility of local health care delivery systems, including state and local health officials, and those surgeons who have direct responsibility to their patients. To assist hospitals in making these decisions, CMS has provided a framework for hospitals and clinicians to implement immediately during the COVID-19 response, including a list of factors to be considered as to whether planned surgery should proceed. These factors include:

- current and projected COVID-19 cases in the facility and region;
- supply of PPE to the facilities in the system;
- staffing availability;
- bed availability, especially intensive care unit beds;
- ventilator availability;
- health and age of the patient, in the context of the risks of concurrent COVID-19 infection during recovery; and
- urgency of the procedure.

CMS has also recommended that non-essential dental exams and procedures be postponed due to the close proximity of health care provider to the patient. In an effort to reduce in-person visits for seniors, and in turn reduce their risk of exposure to COVID-19, CMS has expanded telehealth benefits for Medicare beneficiaries.
Surveys. CMS previously announced that during the COVID-19 outbreak, survey activity would be limited to immediate jeopardy complaints, complaints alleging infection control concerns, statutorily required recertification, revisits necessary to resolve enforcement actions, and initial certifications (see CMS issues Coronavirus protection, prevention guidance for hospitals and nursing homes, March 5, 2020). More recently, CMS has narrowed the focus of its surveys to include only immediate jeopardy complaint inspections, targeted infection control inspections, and self-assessments. Complaint inspections and infection control inspections will both be conducted using streamlined review tools and checklists to minimize the impact on provider activities, while ensuring providers are implementing actions to protect health and safety. These new focused inspection tools for inspectors operationalize the latest guidance from CMS and CDC to control and prevent the spread of COVID-19, and during the inspection process, CMS will work with providers and inspectors to provide additional training related to infection control. The infection control checklist used during inspections will also be shared with providers and suppliers. CMS encourages provider to utilize the checklist to conduct a self-assessment of the facility’s ability to prevent the spread of COVID-19. For any inspections that are delayed due to the reprioritization of resources, CMS will use enforcement discretion, unless an immediate jeopardy situation arises.

Protecting Employees

Many of the same actions that are used to protect patients from the spread of infection will also help protect employees from becoming infected. In the initial guidance notices for hospitals and nursing homes, CMS advised that hospital staff should be screened in the same manner as visitors to determine whether they have traveled internationally within the last 14 days to restricted countries, had contact with someone with known or suspected COVID-19, or if they have a fever or symptoms of a respiratory infection, such as cough and sore throat (see CMS issues Coronavirus protection, prevention guidance for hospitals and nursing homes, March 5, 2020). Providers who have signs and symptoms of a respiratory infection should not report to work. Any staff that develop symptoms while on the job should immediately stop work, put on a facemask, self-isolate at home, and inform the hospital’s infection preventionist.

PPE. Due to the overwhelming need for, and shortage of, respirators, the CDC has updated its PPE recommendations for health care workers involved in the care of patients with known or suspected COVID-19 (see New coronavirus infection control guidance for facilities, home health providers, March 11, 2020). CMS surveyors will consider these recommendations to determine if Medicare and Medicaid providers and suppliers are complying with infection control protocols. Health care providers should wear eye protection, a medical gown, and gloves when treating patients with known or suspected COVID-19. Airborne infection isolation rooms (AIIRs) should be reserved for patients undergoing aerosol-generating procedures, while other patients with known or suspected COVID-19 should be cared for in a single-person room with the door closed. Based on local and regional situation analysis of PPE supplies, facemasks may be an acceptable temporary alternative when the supply chain of respirators cannot meet the demand. If limited respirators are available, they should be prioritized for procedures that are likely to generate respiratory aerosols, which would pose the highest exposure risk to health care providers. The FDA approved the CDC’s request for an emergency use authorization to allow health care personnel to use certain National Institute for Occupational Safety and Health (NIOSH) approved respirators during the COVID-19 outbreak in health care settings. While these respirators do not meet the FDA’s requirements, they may be effective in preventing health care personnel from airborne exposure, including COVID-19, which can cause serious or life-threatening disease, including severe respiratory illness. Allowing the use of these NIOSH-approved respirators in a health care setting will maximize the number of respirators available to meet the needs of the health care system. Once the supply chain is restored, facilities should return to the use of FDA-approved respirators.

Moving Forward

The COVID-19 outbreak is a pandemic like most have never experienced in their lifetimes, and the response to it is constantly evolving and changing as we learn more about the disease and our ability to control the spread.
With the situation rapidly changing, it is important for health care providers to stay aware of compliance-related guidance and updates from the agencies. It’s also important for providers to protect patient health, patient health information, and employees while being ready to adapt to quickly changing requirements and guidance.

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