Federal and State Assistance

- Considerations
  - The federal government has funded several programs to assist providers in the wake of the COVID-19 pandemic, including:
    - Paycheck Protection Program
    - Medicare Advance Payments
    - Provider Relief Fund
    - FEMA Assistance
Each of these programs has specific eligibility and performance requirements, including attestation and documentation requirements.

- States also are providing relief and support for providers. These programs also have specific eligibility and performance requirements.

**Response**

- Ensure the organization can demonstrate that it satisfies all eligibility requirements prior to application to any assistance program; compile and confirm the accuracy of all information submitted with application.
- Understand all conditions for the use of any funds, and develop processes to ensure compliance with those conditions.
- Develop and execute processes to track and document all fund uses.
- Ensure completeness and accuracy of all reports submitted to any government entity or lending institution regarding use of funds; ensure timely and appropriate response to any queries from same.

**HIPAA Waivers**

- **Privacy Considerations**
  - The organization has processes in place to track the timeframe to meet the requirements for the short-term waiver of HIPAA penalties once the disaster protocol has been instituted.

- **Response**
  - Ensure a hospital’s documented process is in place to demonstrate that certain sharing of PHI outside of the HIPAA Privacy Rule requirements is applied to situations which meet all of the following conditions:
    1. Only in areas covered by the public health emergency
    2. Only for hospitals that have implemented their disaster protocol
    3. Only for a period of 72 hours from the time the disaster protocol is implemented

  - **WAIVER CONSIDERATION:** The waiver information addresses the requirement for hospitals to have written policies on patient visitation. This waiver applies only to hospitals in states with 51 or more confirmed cases of COVID-19, and applies only to visitation of patients in COVID-19 isolation. In addition, hospitals in states with 51 or more confirmed cases of COVID-19 now have an extended timeframe in which to provide requested medical records to patients.

- **42 CFR Part 2 Provisions of the CARES Act**
  - **Considerations**
    - The organization has reviewed, revised, and implemented its Substance Use Disorder (SUD) Confidentiality and Disclosure policies for 42 CFR Part 2 program (Part 2) information to meet the amendments provided in the CARES Act and ensure policies align with the HIPAA rules.

  - **Response**
    - Develop or update organizational processes to ensure the provisions of the CARES Act for 42 CFR Part 2 SUD information are in place.
    - Routinely audit use and disclosure of Part 2 information to ensure that the CARES Act
provisions have been appropriately implemented.

**CMS Waivers and Flexibilities**

- **Considerations**
  - The Centers for Medicare & Medicaid Services (CMS) has issued numerous Section 1135 blanket waivers of specific regulatory requirements to ease administrative burden. Also, CMS has published an Interim Final Rule easing other requirements. A complete summary of CMS’ actions may be found on its Coronavirus Waivers and Flexibilities [web page](https://www.cms.gov/coronavirus).
- **Response**
  - Ensure managers are aware of those waivers and flexibilities applicable to their operations.
  - Develop policies for documenting use of the waivers when changing established operations.
  - Develop process for unwinding arrangements dependent upon waivers and flexibilities following the end of the COVID-19 public health emergency.

**Emergency Disaster Protocols**

- **Considerations**
  - The organization has adequate emergency disaster protocols.
- **Response**
  - Develop or update the emergency disaster protocol to ensure it is multi-disciplinary and multi-agency.
  - Conduct tabletop exercises to test the protocols.
  - Revise protocols as necessary to adequately address emergency disaster plans and response.
  - WAIVER CONSIDERATION: CMS waivers address the requirement to develop and implement emergency preparedness policies and procedures for surge sites at hospitals and Critical Access Hospitals (CAHs). This addresses the current requirements for a communication plan that includes all staff, entities providing services under the arrangement, patients’ physicians, other hospitals and CAHs, and volunteers.

**EMTALA Waiver**

- **Considerations**
  - The organization has a process for the relocation of individuals for screening at alternative locations, as well as the transfer of individuals who have not been stabilized.
- **Response**
  - Develop and implement a documented process that meets the requirements of the EMTALA Waiver if alternative locations will be used for screening pursuant to the state’s emergency preparedness plan. This should be done upon activation of the organization’s disaster plan.
  - Develop and implement a documented process for the transfer of an individual who has not been stabilized, if the transfer is necessitated by the circumstances of the declared federal public health emergency for the COVID-19 pandemic.
  - Document both the EMTALA Waiver activation and any patient transfers in the medical record, and monitor regularly to ensure waiver requirements are met.
  - WAIVER CONSIDERATION: The waivers address the requirement for written policies and procedures for emergency services at off-campus hospital departments at surge facilities only. This relates to the assessment, initial treatment, and referral of patients.
NOTE: While a facility can inform patients of alternative treatment locations, once a patient presents to an Emergency Department (ED), EMTALA applies and the medical screening examination must be provided at that location.

Telehealth Waivers

Refer to PYA’s summary of the rules regarding Medicare coverage for telehealth and communication technology-based services.

Provider Credentialing and Licensing

- Considerations
  - The organization has a process in place to allow for provisional credentialing to expedite the ability to provide necessary patient care services.

- Response
  - Develop and implement a process for expedited credentialing, orientation, and onboarding of supplemental staff or shared staff.
  - Ensure the organization has a policy that establishes the threshold for use and priority listing for supplemental staff (e.g., shared organizational staff, followed by similarly credentialed and licensed staff, followed by Medical Reserve Corps, etc.).
  - WAIVER CONSIDERATION: CMS waivers address the requirement that a physician or non-physician practitioner be licensed in the state in which he/she is furnishing services. The waivers also address the application fees for prospective and revalidating institutional providers, fingerprint-based criminal background checks, and on-site visits and reviews of providers or suppliers. Additionally, CMS is postponing revalidation actions.

Physician Financial Arrangements—Stark Law Waivers

- Considerations
  - The organization has a plan in place to address necessary changes in physician compensation methodology that is based on a productivity-based compensation formula adversely affected by postponement of elective surgeries and decreased outpatient visits.
  - This includes preparing employment agreements and documentation of short-term compensation arrangements with physicians who are hired or redeployed to help in the medical response crisis.
  - The organization has a plan in place to evaluate appropriate application of blanket waivers to other physician relationships including real estate, professional service arrangements, and non-monetary compensation.

- Response
  - Prepare for rapid decision-making for physician employment issues, including compensation adjustments, retention arrangements, hiring decisions, and patient care assignment changes.
  - Evaluate processes to redeploy certain employed procedural specialists, while also providing reasonable and justifiable compensation.
  - Ensure that all conditions of each blanket waiver are appropriately understood and satisfied in order to rely on the resulting flexibility and relief.
  - Ensure reliance on any waiver or modifications to any process subject to the Stark Law and Anti-Kickback Statute has appropriate approvals and supporting documentation.
○ WAIVER CONSIDERATION: Providers may request from CMS specific individual waivers to certain requirements under Stark, but must be able to address the dissolution of these actions upon the end of the public health emergency.
○ See PYA’s Stark Law Blanket Waiver Checklist.

Medicare Provider Enrollment Relief

- Considerations
  ○ The organization has a process in place to accommodate provisions for emergency provider enrollment in Medicare in order to meet patient care needs.
- Response
  ○ Secure the necessary provider information to initiate temporary billing privileges in accordance with the Medicare Provider Enrollment Relief provisions, including, but not limited to, the following:
    1. Legal name
    2. National Provider Identifier (NPI)
    3. Social Security number
    4. A valid in-state or out-of-state license
    5. Address
    6. Contact information (i.e., telephone number)
  ○ Ensure the organization has a process in place to document all emergency provisions used during the COVID-19 crisis and complete an enrollment application for full Medicare billing privileges once the public health emergency declaration is lifted.
  ○ WAIVER CONSIDERATION: CMS issued an unprecedented array of temporary regulatory waivers and new rules to allow hospitals and healthcare systems to deliver services at other community-based locations to make room for COVID-19 patients needing acute care in their main facilities. The changes complement and augment the work of FEMA and state and local public health authorities by empowering hospitals and healthcare systems to rapidly expand treatment capacity and separate infected from uninfected patients.

Alternative/Additional Use of Staff

- Considerations
  ○ The organization has a documented process in place to provide for the use of staff in alternative positions, or the use of unlicensed staff as allowed by state statute.
- Response
  ○ Develop and implement a process to use available staff (i.e., in alternative positions and, as state executive orders allow, by engaging unlicensed temporary staff) where needed during the emergency period.
  ○ Employ a robust monitoring program related to the use of staff in such a manner to ensure proper patient care is delivered and documented.

Patient Access Staffing and Adjusted Responsibilities

- Considerations
  ○ The organization has a plan in place to accommodate a dramatic increase in patients entering the facilities, as well as patients needing to cancel appointments and procedures, all requiring additional patient access staff, technology, personal protective equipment
(PPE), and training.

- **Response**
  - Ensure the organization’s disaster plan provides for alternative staffing for patient access, as well as adaptable technology. Additionally, develop and provide training to re-allocated staff for patient access services.

**Telecommuting**

- **Non-essential employees working from home**
  - **Considerations**
    - The organization has processes in place that allow non-essential employees to work from home and ensure that confidential and proprietary information is safeguarded.
  - **Response**
    - Ensure the organization has a plan for resources, communications, expense reimbursement, etc.
    - Review insurance policies (e.g., employee benefits, workers compensation, cyber, etc.) to ensure appropriate and adequate coverage.
    - Confirm IT infrastructure can support remote work and that data privacy and security is ensured with work-from-home arrangements consistent with the organization’s information security policies and procedures.
    - Implement additional auditing of privacy and security safeguards, and regularly provide employees critical reminders.

**Research activities**

- **Considerations**
  - The organization has a process in place to pause face-to-face research activities except those that affect the safety and well-being of the subjects, or those related to COVID-19.
  - The organization has a process in place to review and approve studies and funding related to COVID-19 research.
- **Response**
  - Notify the affected individuals of the required pause in current research studies involving human subjects, as deemed appropriate based on COVID-19 guidance.
  - Ensure a process is in place to review and approve research opportunities specifically related to COVID-19.
  - Incorporate detailed auditing of COVID-19 studies into the compliance work plan to ensure that funding sources are appropriately vetted, new research programs are based on scientific and societal needs, and the study complies with existing clinical study requirements.

**Documentation, Coding, and Billing**

- **Considerations**
  - The organization has processes in place to meet the expanded use of telehealth, including appropriate documentation and the accurate use of procedure codes, modifiers, and place of service.
  - The organization has processes in place to facilitate appropriate billing for all COVID-19-related treatment.
The organization has a process in place to meet requirements to post its cash price for COVID-19 testing on its public website.

- The organization has processes in place to manage a significant increase in uncompensated care and to track costs for delivering COVID-19-related care for the uninsured.
- The organization has a process to ensure patients are not “balance billed” for COVID-19-related testing and treatment.

**Response**

- Implement processes to accurately provide telehealth and COVID-19-related services, including documentation, coding, and billing.
- Develop a plan to assist patients with financial clearance to determine if they are eligible for charity, Medicaid, or other insurance.
- For uninsured patients, track COVID-19-related testing and treatment costs for proper billing and reimbursement under the CARES Act.
- Review financial assistance policies to ensure that any adjustments made during a public health emergency are clearly delineated both as to application and the time period for the adjustment to be in place.

**Law Enforcement–Privacy, Protection from Exposure**

- **Considerations**
  - The organization has a process in place to appropriately disclose protected health information (PHI) about an individual who has been infected with or exposed to COVID-19 to law enforcement, paramedics, other first responders, and public health authorities in compliance with the HIPAA Privacy Rule.

- **Response**
  - Disclose PHI, such as the name or other identifying information about individuals, to law enforcement and first responders without a HIPAA authorization in the following situations:
    1. When needed to provide treatment
    2. When required by law
    3. When first responders may be at risk for an infection
  2. When disclosure is necessary to prevent or lessen a serious and imminent threat
    - Ensure a process is in place that provides guidance regarding the disclosure of PHI to first responders and others to ensure appropriate precautions are employed, such as the use of PPE.

**Theft of Personal Protective Equipment (PPE)**

- **Considerations**
  - To maximize the protection of healthcare workers, the organization must have security processes in place to protect PPE from theft.

- **Response**
  - Make physical security of PPE a key consideration for all healthcare provider organizations. Ensure robust inventory and distribution processes, including an audit of receipt and restocking, are in place to monitor and safeguard PPE, to ultimately protect front-line healthcare workers.

**Patient Service Organizations (PSO) Incident Reports**
• Considerations
  ○ The organization has a process in place to collect data on incidents (patients, visitors, etc.) and associated events related to COVID-19 exposure and treatment in the Patient Safety Evaluation System (PSES) and to identify issues of patient safety and quality improvement to be evaluated under the Patient Safety Act.

• Response
  ○ Evaluate and update the PSES intake tool to ensure that appropriate COVID-19 data is collected for analysis by the PSO.

Vendor Due Diligence

• Considerations
  ○ The organization has a process in place to protect against faulty/inferior/unsafe products and services and to confirm that products offered by vendors are registered with the Food and Drug Administration (FDA).
  ○ The organization has a process in place to document any exceptions made to its vendor policies and purchasing decisions.

• Response
  ○ Ensure that products are registered with the FDA, with the exception of items temporarily permitted for emergency use in healthcare by the Centers for Disease Control (CDC), i.e., industrial N95s.
  ○ Document all allowed exceptions to existing vendor policies and purchasing decisions, and communicate these to administration, medical staff, nursing staff, pharmacy staff, the purchasing department, and key stakeholders.

Email and Marketing Schemes

• Considerations
  ○ The organization has a process in place to detect email and marketing scams related to COVID-19 including:
    • A workforce trained in using caution with email attachments, and avoiding social engineering and phishing scams.
    • The recognition and use of trusted sources, such as government websites, for information, rather than unknown sources purporting to provide financial, product, and services assistance.
    • The verification of authenticity of electronic data received by the organization through use of malware and virus protection software

• Response
  • Ensure policies and procedures are in place to monitor, identify, and protect important systems supporting COVID-19 response efforts.

Prescription Fraud

• Considerations
  ○ The organization has a process in place to monitor and detect prescription drug fraud and diversion of anti-viral drugs associated with the COVID-19 response.

• Response
  ○ Ensure a process is in place to monitor, detect, mitigate, and report, as required,
prescription drug fraud.

**Cyber-Security**

- **Considerations**
  - The organization has a process in place to identify and mitigate risk from Advanced Persistent Threat (APT) groups who use the COVID-19 pandemic as part of their cyberattack operations, such as coronavirus-themed phishing messages or malicious applications.
  - The organization has a process in place to address application of the HIPAA Rules to other areas of healthcare outside of telehealth during the COVID-19 pandemic.

- **Response**
  - Revise and implement organizational risk mitigation policies and procedures to address identification of COVID-19-related cyberattacks and provide training to its workforce regarding the same.
  - Implement organizational policies and procedures regarding HIPAA violations, beyond telehealth waivers, of privacy, security, and breach notification rules.

**Other Considerations**

Guidance for other areas subject to compliance implications is also available, including:

- Data sharing with state and federal officials
- Infection control considerations
- Management of elective procedures
- Extension of quality and cost report filing deadlines

If you have COVID-19 regulatory-compliance-related questions or would like additional pandemic guidance, visit PYA’s COVID-19 hub, or contact one of our PYA executives below at (800) 270-9629.