New Compliance Trends for Compliance Officers

Georgia Hospital Association
Compliance Officers Roundtable Virtual Meeting

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Introductions

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Key Compliance Risks Facing Healthcare Organizations

So Many Risks, So Little Time…

- Physician financial arrangements
- Contract management
- Advanced technologies
- Vendor management
- Telemedicine
- Interoperability/Information Blocking
- Compliance program due diligence
  - Training
  - Exclusion checks
  - Conflict of interest
- HIPAA privacy and security
  - Patient access
  - Information sharing
  - Cyberattacks
  - Remote workers
- Back end revenue cycle operations
- Emergency preparedness
- OSHA Temporary Emergency Standards
- Price Transparency

Agenda

1. OSHA Emergency Temporary Standard
2. Price Transparency
3. Compliance Program Due Diligence
    - Contract Management Considerations
    - Exclusion Screenings
4. Proposed E/M Changes
5. Alternative Physician Compensation Arrangements

Agenda (continued)

6 2021 Physician Fee Schedule Impact

7 Advanced Practice Provider Considerations

8 Provider Needs Assessments

9 COVID-19 Checklist Update

OSHA Emergency Temporary Standard

What is the Emergency Temporary Standard (ETS)?

- Issued by OSHA to protect healthcare workers and healthcare support services workers from occupational exposure to COVID-19 in settings where people with COVID-19 are reasonably expected to be present
- Based on requirements of the Occupational Safety and Health Act (OSH Act) and legal precedent under the Act
- OSHA “shall issue an ETS if the agency determines that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and an ETS is necessary to protect employees from such danger.”

Key Dates

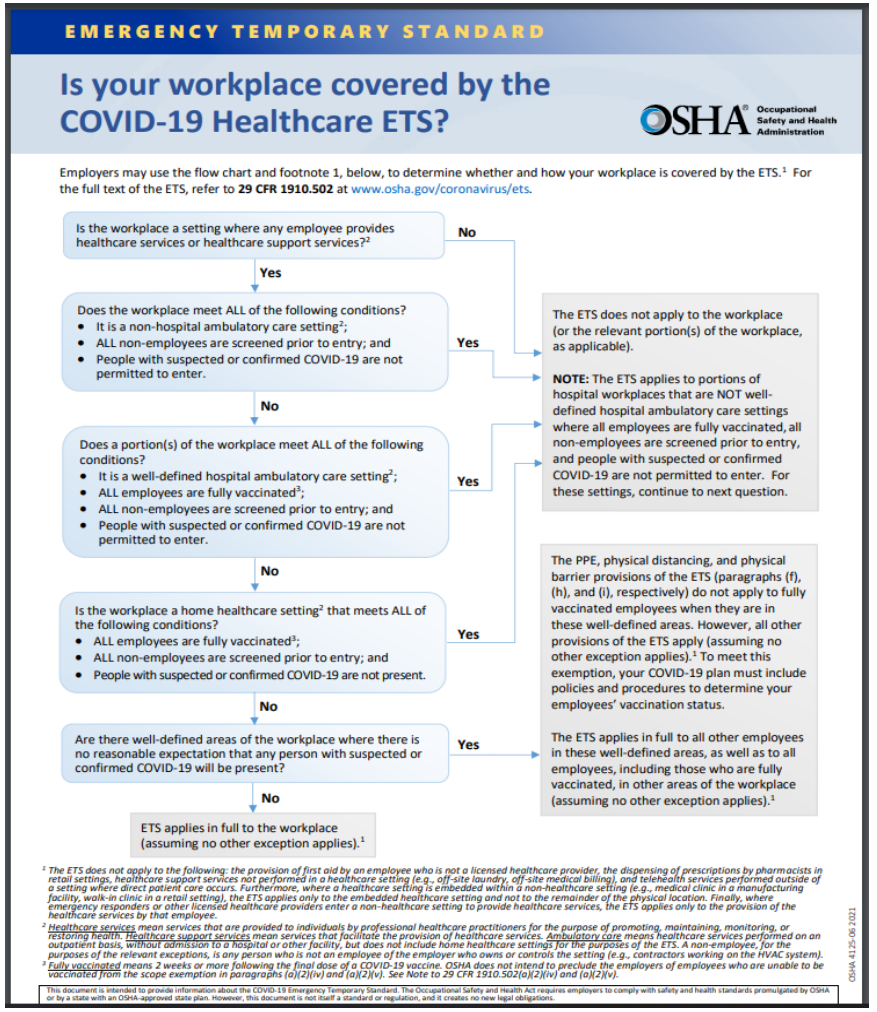
- Issued June 10, 2021
- Effective date June 21, 2021
- Deadlines for implementation of ETS
  - July 6, 2021 - all standards except three items
  - July 21, 2021 - physical barriers, building ventilation, and training
- Deadlines for comments
  - July 21, 2021 – initial deadline
  - August 20, 2021 – extended deadline
    - AHA submitted comments on August 20 urging OSHA to withdraw ETS interim final rule or if agency declines to do so, we recommend that the ETS be allowed to expire at the end of the six months and not be published as a final rule

Who Does The ETS Apply to?

- Hospitals
- Ambulatory Care Facilities
  - Physician Offices
  - Specialty Care Clinics
  - Ambulatory Surgery Centers
  - Urgent Care Centers
- Home Healthcare
- Emergency Responders & Prehospital Care
- Long-term Care

There are Some Exceptions…

- Provision of first aid by an employee who is not a licensed healthcare provider
- Dispensing of prescriptions by pharmacists in retail settings
- Healthcare support services not performed in a healthcare setting (e.g., offsite laundry, off-site medical billing)
- Telehealth services performed outside of a setting where direct patient care occurs
- Non-hospital ambulatory care setting where all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are not permitted to enter those settings
- Well-defined hospital ambulatory care settings where all employees are fully vaccinated and all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are not permitted to enter those settings
- Home healthcare settings where all employees are fully vaccinated and all non-employees are screened prior to entry and people with suspected or confirmed COVID-19 are not present



EMERGENCY TEMPORARY STANDARD

Is your workplace covered by the COVID-19 Healthcare ETS?

OSHA Occupational Safety and Health Administration

Employers may use the flow chart and footnote 1, below, to determine whether and how your workplace is covered by the ETS.[1] For the full text of the ETS, refer to **29 CFR 1910.502** at www.osha.gov/coronavirus/ets.

Is the workplace a setting where any employee provides healthcare services or healthcare support services?[2]

No → The ETS does not apply to the workplace (or the relevant portion(s) of the workplace, as applicable).

Yes

Does the workplace meet ALL of the following conditions?
- It is a non-hospital ambulatory care setting[2];
- ALL non-employees are screened prior to entry; and
- People with suspected or confirmed COVID-19 are not permitted to enter.

Yes → The ETS does not apply to the workplace (or the relevant portion(s) of the workplace, as applicable).

NOTE: The ETS applies to portions of hospital workplaces that are NOT well-defined hospital ambulatory care settings where all employees are fully vaccinated, all non-employees are screened prior to entry, and people with suspected or confirmed COVID-19 are not permitted to enter. For these settings, continue to next question.

No

Does a portion(s) of the workplace meet ALL of the following conditions?
- It is a well-defined hospital ambulatory care setting[2];
- ALL employees are fully vaccinated[3];
- ALL non-employees are screened prior to entry; and
- People with suspected or confirmed COVID-19 are not permitted to enter.

Yes → The PPE, physical distancing, and physical barrier provisions of the ETS (paragraphs (f), (h), and (i), respectively) do not apply to fully vaccinated employees when they are in these well-defined areas. However, all other provisions of the ETS apply (assuming no other exception applies).[1] To meet this exemption, your COVID-19 plan must include policies and procedures to determine your employees' vaccination status.

No

Is the workplace a home healthcare setting[2] that meets ALL of the following conditions?
- ALL employees are fully vaccinated[3];
- ALL non-employees are screened prior to entry; and
- People with suspected or confirmed COVID-19 are not present.

Yes → The PPE, physical distancing, and physical barrier provisions of the ETS (paragraphs (f), (h), and (i), respectively) do not apply to fully vaccinated employees when they are in these well-defined areas. However, all other provisions of the ETS apply (assuming no other exception applies).[1] To meet this exemption, your COVID-19 plan must include policies and procedures to determine your employees' vaccination status.

No

Are there well-defined areas of the workplace where there is no reasonable expectation that any person with suspected or confirmed COVID-19 will be present?

Yes → The ETS applies in full to all other employees in these well-defined areas, as well as to all employees, including those who are fully vaccinated, in other areas of the workplace (assuming no other exception applies).[1]

No → ETS applies in full to the workplace (assuming no other exception applies).[1]

[1] *The ETS does not apply to the following: the provision of first aid by an employee who is not a licensed healthcare provider, the dispensing of prescriptions by pharmacists in retail settings, healthcare support services not performed in a healthcare setting (e.g., off-site laundry, off-site medical billing), and telehealth services performed outside of a setting where direct patient care occurs. Furthermore, where a healthcare setting is embedded within a non-healthcare setting (e.g., medical clinic in a manufacturing facility, walk-in clinic in a retail setting), the ETS applies only to the embedded healthcare setting and not to the remainder of the physical location. Finally, where emergency responders or other licensed healthcare providers enter a non-healthcare setting to provide healthcare services, the ETS applies only to the provision of the healthcare services by that employee.*

[2] *Healthcare services mean services that are provided to individuals by professional healthcare practitioners for the purpose of promoting, maintaining, monitoring, or restoring health. Healthcare support services mean services that facilitate the provision of healthcare services. Ambulatory care means healthcare services performed on an outpatient basis, without admission to a hospital or other facility, but does not include home healthcare settings for the purposes of the ETS. A non-employee, for the purposes of the relevant exceptions, is any person who is not an employee of the employer who owns or controls the setting (e.g., contractors working on the HVAC system).*

[3] *Fully vaccinated means 2 weeks or more following the final dose of a COVID-19 vaccine. OSHA does not intend to preclude the employers of employees who are unable to be vaccinated from the scope exemption in paragraphs (a)(2)(iv) and (a)(2)(v). See Note to 29 CFR 1910.502(a)(2)(iv) and (a)(2)(v).*

This document is intended to provide information about the COVID-19 Emergency Temporary Standard. The Occupational Safety and Health Act requires employers to comply with safety and health standards promulgated by OSHA or by a state with an OSHA-approved state plan. However, this document is not itself a standard or regulation, and it creates no new legal obligations.

OSHA 4125-06 2021

ETS Components - Healthcare

COVID-19 plan

Hazard assessment

Patient screening & management

Standard & transmission-based precautions

Physical distancing

Physical barriers

Cleaning & disinfection

Ventilation

Vaccination

Training

Recordkeeping

Personal protective equipment

Health screening & medical management

Anti-retaliation & requirements implemented at no cost to employees

Reporting COVID-19 fatalities & hospitalizations to OSHA

COVID-19 Plan

- Develop a plan specific to each workplace
  - May be developed by workplace type rather than individual workplace if substantially similar as long as site-specific information is included
  - May develop one comprehensive plan if employees are performing the same task(s) at different facilities
- Must be in writing for organizations with more than 10 employees
- Designate at least one safety coordinator to implement and monitor
  - Must be knowledgeable in infection control practices
  - Identity must be documented in any written COVID-19 plan
  - Must have authority to ensure compliance
  - Responsibilities could include conducting regular inspections
  - Safety coordinator(s) will be interviewed during OSHA inspection

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COVID-19 Plan (cont.)

- Must be monitored and updated as needed
- Must seek input and involvement of non-managerial employees
- Include specific policies and procedures to identify and mitigate hazards
- Citations can be issued for elements of the COVID-19 plan which are not implemented

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Hazard Assessment

- Part of the COVID-19 plan
- Must be conducted to identify potential workplace hazards
- Provides a framework for plan implementation
- Inspect entire workplace and address employees' potential exposure to all people present
- Team-based approach – management, employees, others
- Have flexibility to determine best approach to conducting the overall assessment
- OSHA inspector should determine through private interviews if non-managerial employees and their representatives had input into the hazard assessment and COVID-19 plan development

Training

- Must be provided to all employees
- Must be offered in language and literacy levels every employee can understand, speak, and read
- Curriculum must include at least:
  - Transmission of COVID-19
  - Workplace risks that could result in infection
  - Employer specific policies and procedures for patient screening and management, prevention of spread (precautions, physical distancing, physical barriers), PPE, cleaning and disinfection, ventilation, health screening and medical management, vaccination
  - Multi-employer workplace agreements
  - Available sick leave policies
  - Identity of safety coordinator
  - Other items

Training (cont.)

- Additional training is required if:
  - Changes occur that affect employees' risk
    - New job tasks
    - As a result of outbreak
    - New available information from CDC, WHO, or OSHA, local health departments
  - Policies and procedures change
  - Employer believes the skill and/or understanding was not retained through initial training
- Training must be overseen or conducted by person knowledgeable in the subject matter as it relates to the employee's job duties
- Training must provide an opportunity for interactive questions and answers

Recordkeeping

- Applies to organizations with more than 10 employees
- Retain all versions of COVID-19 plan implemented while ETS remains in effect
- Establish and maintain a log to record each instance identified in which an employee is COVID-19 positive regardless of whether instance is connected to exposure at work
  - Must contain employee's name, one form of contact information, occupation and work location, date of last day at work location, date of positive test or diagnosis, date employee first experienced symptoms, if any
  - Information must be recorded within 24 hours of employer learning the employee is positive
  - Must be maintained as though it is a confidential medical record and not disclosed except as required
  - Must be maintained and preserved while ETS is in effect

Record Keeping (cont.)

- Must provide for examination and copying upon request and by the end of the next business day after the request
  - All versions of written COVID-19 plan to any employees or their personal and authorized representatives
  - Individual log entry for particular employee provided to that employee and to anyone having written authorized consent of that employee
  - Version of COVID-19 log that removes names and other information to any employees or their personal and authorized representatives

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Familiarize Yourself with OSHA Direction

- Provides guidelines and establishes uniform inspection and enforcement procedures
  - https://www.osha.gov/sites/default/files/enforcement/directives/DIR_2021-02_CPL_02.pdf
- Inspections conducted either on-site or combination of on-site and remote methods
- Highest inspection priority given to fatality inspections and “then other unprogrammed inspections”
- Compliance safety and health officers (CSHO) will
  - Conduct an “opening conference” and request to speak with the identified safety coordinator as well as others
  - Review employer’s COVID-19 plan and related documents and conduct interviews with employers and employees
  - Conduct a “walkaround”

Price Transparency

CMS Price Transparency: 2019

- Requirement of the Affordable Care Act
- Effective January 1, 2019
- Requirement: hospitals must post standard charges for all items and services on a public-facing website in a machine-readable format
- Applies to all hospitals, including critical access, inpatient rehab, and inpatient psych
- Revenue codes and charge codes not required
- Concern regarding use of CPT/HCPCS codes (AMA copyright)
- Subsection (d) hospitals (those paid under IPPS) also required to publish charges by DRG

Executive Order: June 24, 2019

- Provided 60 days to develop requirements and propose regulations
- Hospital publication of standard charge information including charges and information based on negotiated rates
- Also post bundled charge information for common or shoppable services
- Provided 90 days for issuance of advance NPRM requiring providers and issuers to facilitate access to information about expected out-of-pocket costs for items or services to patients before they receive them

Hospital Requirements – The First Final Rule

Requirements of the Final Rule: Part 1

Final rule effective January 1, 2021

Requires charge data to be posted in a single machine-readable file

- No barriers to access
  - Free of charge, no account or password required
  - No PHI required to access
- Formats include .XML, .JSON, .CSV
  - .PDF format is not machine readable
- Items and services
  - Includes both individual items and service packages provided to either an inpatient or an outpatient
  - Includes both hospital services and physician/professional fees, if employed by the hospital

Requirements of the Final Rule: Part 1

- Machine-readable file (continued):
  - Individual charge level – both actual charge and payer-negotiated charge
    - Five types of “standard charges”
      - Gross charges – chargemaster rate
      - Payer-specific negotiated rates – applies to all third-party payers other than Medicare and Medicaid fee-for-service
        - Also excludes WC and VA *if non-negotiated*
      - De-identified minimum rates
      - De-identified maximum rates
      - Discounted cash price – for those who pay cash for services

Requirements of the Final Rule: Part 1

- Machine-readable file (continued):
  - Corresponding common billing and accounting codes, as applicable
  - Updated at least annually and show date of last update on file
  - Required of each hospital location if there is a different set of standard charges

Requirements of the Final Rule: Part 2

- Displaying shoppable services
  - Standard charges for at least 300 shoppable services or bundles
  - Defined as a service that can be scheduled by a health care consumer in advance
  - Services selected for display should be those commonly provided to that hospital's patients
  - 70 bundles identified by CMS – provider must have total of at least 300 even if not all 70 are offered at facility
    - Easily searchable and consumer-friendly
- No barriers to access
- Information updated at least annually

Alternative to Shoppable Services

Provider deemed to meet this requirement if it maintains an Internet-based price estimator tool

Must include estimates for any of the identified 70 services as are provided by the hospital plus additional services to total at least 300 shoppable services	Estimator would allow consumer to determine what they will be expected to pay for the service	Prominently displayed on hospital website • Without barriers to access such as a fee, registration or establishing user account

Providers still required to post machine-readable file tied to chargemaster detailing “standard charges”

Price Transparency: Key Compliance Questions/Considerations

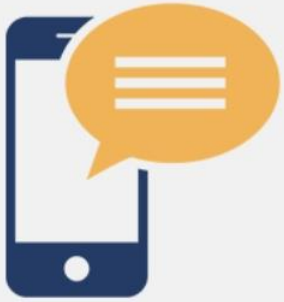
Compliance Concerns

- Capturing pharmacy charges
- Defining third-party payer
- Inclusion of charges for “employed” physicians
  - CMS declined to codify a definition for “employment”
  - Not limited to chargemaster: physician charges may be elsewhere within hospital accounting and billing system or in contracts/rate sheets with third party payers
  - Who establishes and negotiates the charges?
  - Who retains the payments for professional services?

Compliance Concerns

- Potential per day penalty for non-compliance – $300
  - Likely to first receive initial written warning
  - Request for corrective action plan
- Non-compliance noted on CMS website
  - September 24 Executive Order calls for posting within 180 days of order
  - New CMS transparency webpage asks consumers/others to report non-compliance

Consumer Reporting



Contact Us

Have a question about Hospital Price Transparency? Email the hospital price transparency team. Can't find your hospital's pricing information online? We want to know. Contact us beginning on January 1, 2021.

Contact Us

Executive Order: September 24, 2020

- Requires HHS to post on Hospital Compare within 180 days –
  - Whether the hospital is in compliance with the Hospital Price Transparency Final Rule
  - Whether, upon discharge, the hospital provides patients with a receipt that includes a list of services received during a hospital stay
  - How often the hospital pursues legal action against patients, including to garnish wages, to place a lien on a patient's home, or to withdraw money from a patient's income tax refund

Price Transparency: Cost Report Revisions – The Second Final Rule

FY2021 Inpatient PPS Final Rule

- Collecting hospitals' median payer-specific negotiated inpatient service charges for Medicare Advantage organizations – TRANSPARENCY!
  - Hospitals to report this data on their Medicare cost reports
    - Cost reporting periods ending on or after January 1, 2021
    - Penalty for non-compliance – future payments at risk
  - CMS intends to use this information to set MS-DRG relative weights beginning with FY2024

Transparency in Coverage – The Third Final Rule

Transparency in Coverage Final Rule

- Requires non-grandfathered group health plans and health insurance issuers make available –
  - Machine-readable and, upon request, printed file – January 2022
    - In-network negotiated rates
    - Billed charges/allowed amounts for out-of-network providers
    - Negotiated rates and historical net prices for drugs
    - Personalized out-of-pocket cost information
    - Applies to rates for all provider types
  - Internet-based self-service tool – January 2023
    - 500 shoppable services
  - Expanded self-service tool – January 2024
    - All other procedures, services, drugs, DME, etc.
- Final rule posted October 29

Proposed 2022 Price Transparency: Penalty

- Civil monetary penalty for non-compliance
  - Currently $300 per day
  - Proposal based on hospital bed size –
    - Be

TABLE 63: Proposed Application of CMP Daily Amounts for Hospital Noncompliance for CMPs Assessed in CY 2022 and Subsequent Years.

Number of Beds	Penalty Applied Per Day	Total Penalty Amount for full Calendar Year of Noncompliance
30 or less	$300 per hospital	$109,500 per hospital
31 up to 550	$310 - $5,500 per hospital (number of beds times $10)	$113,150 - $2,007,500 per hospital
>550	$5,500 per hospital	$2,007,500 per hospital

Note: In subsequent years, amounts adjusted according to 45 CFR 180.90(c)(3).

Price Transparency: Other Issues

- Deems state forensic hospitals as having met transparency requirements
- Prohibits barriers to access of machine-readable file, including automated searches and direct downloads
- Price estimators would need to fulfill the shoppable services requirement
  - Expected output: cost estimate of the amount expected to be paid by the patient
    - Considers insurance coverage
    - Application to uninsured patients

Price Transparency: Other Issues

- Request for comment related to future rulemaking
  - Expectations for plain language descriptions of shoppable services
  - Best practices for cost estimators
  - Recognizing “exemplar” hospitals
  - Standardization of machine-readable files

Compliance Program Due Diligence

Contract Management

- **Risks**
  - Non-compliance with contract terms
  - Unintentional auto-renewals due to missed cancellation notices or deadlines
  - Missed contract obligations
  - Inefficient workflow processes
  - Failure of an audit due to missing key elements of an audit trail
  - Version control problems
  - Physician Owned Entities

- **Controls**
  - A central electronic repository to manage required documentation
  - Standardized and automated processes for contract execution, review, approval, and renewal
  - Monitoring and auditing of contracts to ensure that regulatory and policy requirements are met prior to payment of or receipt of remuneration
  - Adequate oversight of outsourced services

Vendor Management

- **Risks**
  - Conflicts of interest
  - Excluded vendors
  - Contractual non-compliance
  - Management of vendors as Business Associates

- **Controls**
  - Ethical standards and rules of engagement for all vendors
  - Assure that no vendors are excluded entities
  - Robust procurement process
    - Accountability
    - Contract language standardization
    - Invoice controls
    - Monitoring and auditing of high-risk vendor relationships
    - Contract termination process
  - Create a third party or vendor management checklist:
    - Reference checks
    - Financial solvency
    - Liability coverage
    - Regulatory compliance
    - Verification of delivery, service, and expertise

COI/Exclusion Checks/Other

- **Risks**
  - Compliance training for the workforce, including employees, medical staff, volunteers, students and vendors
  - Exclusion from Medicare and Medicaid
  - Conflict of interest, financial relationship disclosure process and Open Payments verification
  - Risk assessment and compliance work plan
  - Staff competency and credibility

- **Controls**
  - Onboarding and annual training is provided, monitored, and kept up-to-date
  - Exclusion checks are done prior to hiring or contracting and monthly thereafter
  - Conflict of interest statements are obtained initially and annually
  - A risk assessment is conducted at least annually resulting the compliance work plan
  - Compliance staff are competent to carry out duties and are provided regular educational opportunities

Excluded Providers – A Case Study

Exclusions Checks – A Case Study

- Large multi-hospital health system with an employed physician group and a Medicare Advantage plan
- Strong policy regarding the handling of exclusion checks upon hire and monthly thereafter
- Screening outsourced to a third party vendor
- Screening based on data provided by IT in conjunction with HR
- Sanction Screening Process Testing Conducted
  - Limited scope review of new employees
  - Limited scope review of non-credentialed providers

2022 Proposed E/M Changes

E/M Changes

Split/Shared E/M Visits

- Defined as E/M visit provided in facility setting by physician and NPP in same group
- Billed by practitioner who provides >50% total time (who also must sign/date medical record)
- For new/established patients, initial/subsequent visits, prolonged visits, critical care services
- Identify both practitioners in medical record

Critical Care Services

- May provide concurrently to same patient/same day by more than one practitioner representing more than one specialty
- No other E/M visit billed for same patient/same day when services furnished by same practitioner or practitioners in the same specialty and group
- Cannot be reported during same period as procedure with global surgical period

Teaching Physician Services

- Time when teaching physician present can be included in determining E/M level
- For primary care exception, may only use MDM in determining E/M level

Billing for PA Services

- Currently, physician assistants cannot directly bill Medicare; services must be billed by PA's employer
- Consolidated Appropriations Act, 2021, amended relevant provision of Social Security Act to permit direct billing by PAs
  - No change to physician supervision requirement nor the payment percentage (85% of MPFS rate)
- CMS now proposes to amend regulations consistent with CAA provisions

Alternative Physician Compensation Arrangements

Alternative Physician Compensation Arrangements

- ✓ Medical Director
- ✓ On Call Coverage
- ✓ Administrator
- ✓ Vice President of Medical Affairs
- ✓ Chief Medical Information Officer
- ✓ Chief Medical Officer

- ✓ Chief of Staff
- ✓ Section Chief
- ✓ Department Director
- ✓ Teaching Physician
- ✓ Locum Tenens
- ✓ Chief Transformation Officer
- ✓ Chief Administrative Officer

Image Source: Shutterstock.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability

June 9, 2015

Physicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide. Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business. OIG encourages physicians to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.

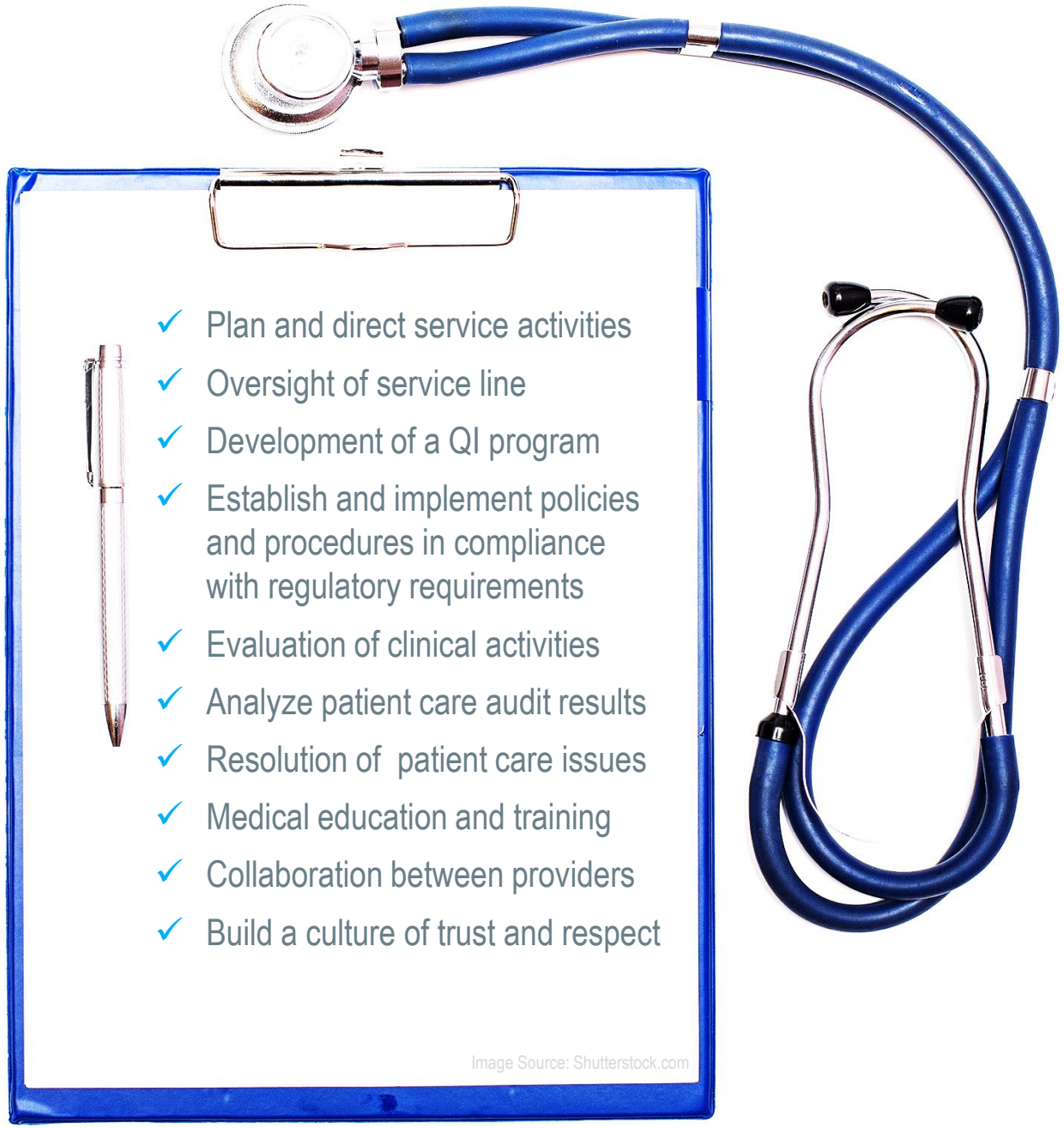
OIG recently reached settlements with 12 individual physicians who entered into questionable medical directorship and office staff arrangements. OIG alleged that the compensation paid to these physicians under the medical directorship arrangements constituted improper remuneration under the anti-kickback statute for a number of reasons, including that the payments took into account the physicians' volume or value of referrals and did not reflect fair market value for the services to be performed, and because the physicians did not actually provide the services called for under the agreements. OIG also alleged that some of the 12 physicians had entered into arrangements under which an affiliated health care entity paid the salaries of the physicians' front office staff. Because these arrangements relieved the physicians of a financial burden they otherwise would have incurred, OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians. OIG determined that the physicians were an integral part of the scheme and subject to liability under the Civil Monetary Penalties Law.

Those who commit fraud involving Federal health care programs are subject to possible criminal, civil, and administrative sanctions. For more information on physician relationships, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf and OIG's "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse" available at http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf.

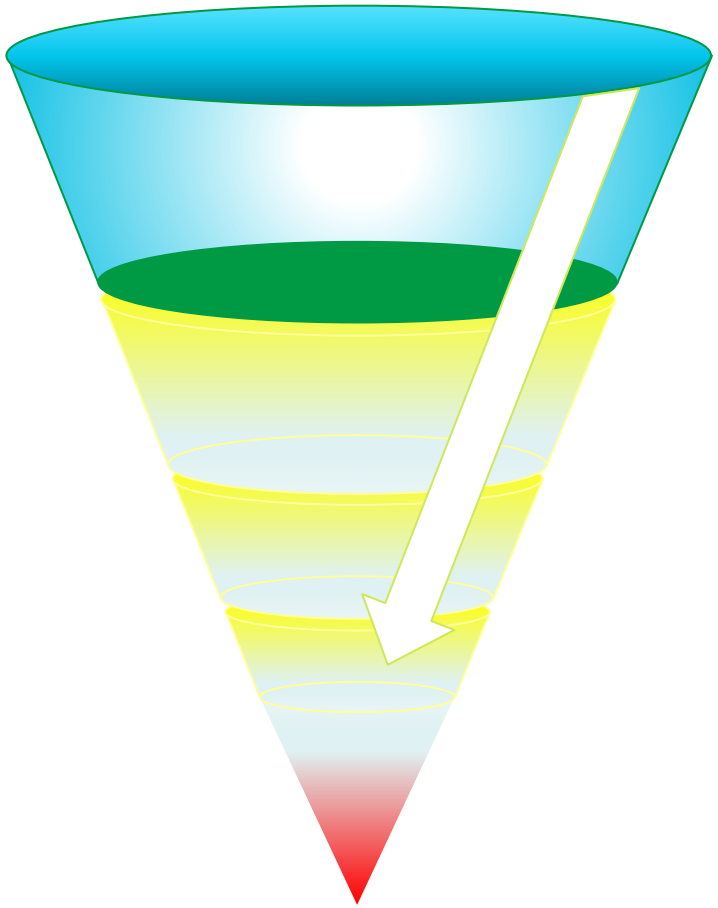
If you have information about physicians or other providers engaging in any of the activities described above, contact the OIG Hotline at https://forms.oig.hhs.gov/hotlineoperations/ or by phone at 1-800-447-8477 (1-800-HHS-TIPS).

Medical Directors

Roles and Expectations



Medical Directors: Need Determination



Determine which medical director positions are required by federal and/or state law and/or otherwise required for regulatory or accreditation purposes.

Evaluate whether market comparisons are available for each identified position. Consider the number of hours provided, the size of the department, and the number of locations overseen by the medical director. Consider additional criteria including, but not limited to, robustness of duties, perceived value to hospital etc.

Consider whether any of the medical directorships cannot be adequately supported based on the information available.

Create the Outline First. . .

- Review, refine, and document the current medical directorship philosophy, focusing on the following:
  - The mission of hospital's medical director program.
  - The process for determining the need for a medical director
  - Maintenance and management of the medical director program, including but not limited to:
    - A policy that requires times sheets for all medical directors be completed and audited monthly
    - A process for when compensation is included in base compensation versus under a separate agreement
    - An annual review of individual medical director arrangements focused on **1)** supporting reasons for continued need, **2)** amount of physician time incurred, and **3)** the resulting accomplishments versus identified expectations
- Create a defined process for determining the need for a medical directorship position versus a managing physician or program director role.
  - Identifying the primary responsibilities for each role and creating a clear distinction in responsibilities for each role eliminates potential for overlapping responsibilities between administrative positions.

2021 Physician Fee Schedule Impact

2021 Medicare Physician Fee Schedule Rulemaking

- 2021 MPFS proposed rule published August 17, 2020 (572 pages + related downloads)
  - Telehealth, care management services, MSSP, QPP, OUD services, FQHC PPS, NCDs, infusion therapy, Part B drugs, MDPP
  - Comment period closed October 5
- 2021 MPFS final rule published December 1, 2020 (2,165 pages + related downloads)
  - Effective January 1, 2021

2020 Final Rule: Time and RVU Changes
Effective 01/01/21

TABLE 20: Summary of Codes and Work RVUs Finalized in the CY 2020 PFS Final Rule for CY 2021

HCPCS Code	Current Total Time (mins)	Current Work RVU 2020	CY 2021 Total Time (mins)	CY 2021 Work RVU
99201	17	0.48	N/A	N/A
99202	22	0.93	22	0.93
99203	29	1.42	40	1.6
99204	45	2.43	60	2.6
99205	67	3.17	85	3.5
99211	7	0.18	7	0.18
99212	16	0.48	18	0.7
99213	23	0.97	30	1.3
99214	40	1.5	49	1.92
99215	55	2.11	70	2.8
G2212	N/A	N/A	15	0.61
G2211	N/A	N/A	11	0.33

Source: https://www.cms.gov/files/document/12120-pfs-final-rule.pdf

Impact - Independent Medical Specialists

- Direct impact to bottom line
- Increase in Medicare reimbursement if primarily an E/M practice
- Potential increase in other payer reimbursement, if other payers utilize reference pricing
- Additional reimbursement could help expand capacity for high risk and rising risk patients, thus increasing ability to participate in value-based models

Impact - Independent Proceduralists

- Direct impact to bottom line
- Decrease in Medicare reimbursement
- Potential decrease in other payer reimbursement, if other payers utilize reference pricing
- **3 options:**
    1. Do more procedures / grow market share
    2. Reduce expenses
    3. Pursue value-based payments

Impact – Employed or Contracted Physicians

Contractual conversion factor <u>does not change</u>
(unless contract subsequently amended or renegotiated)

- **Medical specialists**
  - Increased Medicare reimbursement for the physician's E/M services
  - The same amount of work now produces more wRVUs
  - Employer will pay the physician more compensation for the same amount of work
  - The incremental financial loss is limited to the amount the contracted conversion factor exceeds the actual reimbursement per wRVU received

Impact – Employed or Contracted Physicians

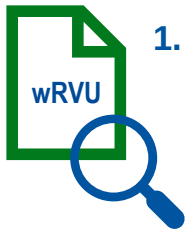
- **Proceduralists**
  - Overall decreased Medicare reimbursement
  - Some increase in total wRVUs due to increase in the RVUs for office/outpatient E/M codes (but far less than medical specialists who provide these services more regularly)
  - Compensation would not be dramatically impacted, as wRVUs will marginally increase and contracted conversion factor will remain the same

Contract Review Challenges

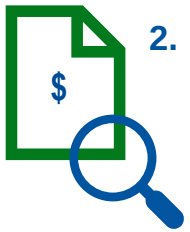
- Benchmark survey data tied to the compensation conversion factor will not fully reflect these impacts for another 2-3 years given normal timing lags in survey data and the varied rate with which contract modifications occur
  - It may be 2023 (based on 2022 data) before benchmark surveys have stabilized from the impact
- Documentation surrounding commercial reasonableness
- Consider compensation structure alternatives
  - Incentivize for managing high-risk and rising-risk patients
  - Reduce healthcare costs
  - Improve patient outcomes

Physician Compensation: Next Steps

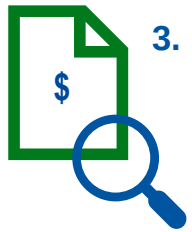
Continue to focus on physician specialties with greater risk of material impact, if necessary, and assess the following:



1. **Estimated wRVU impact**



2. **Estimated physician collections impact**



3. **Estimated physician compensation impact**

4. **Estimated physician net income/loss impact**

5. **Determine physician contract requirements**

Using this data, determine:

- ✓ Do any agreements require adjustment to ensure compensation is fair market value?
- ✓ Do any agreements require adjustment to ensure compensation is commercially reasonable?
- ✓ Are operational losses sustainable?
- ✓ Plan for modifications, if any.

Advanced Practice Provider Considerations

Advanced Practice Provider Considerations

- APPs = Nurse Practitioner (NP), Physician Assistant (PA), Certified Nurse Midwife, Certified Registered Nurse Anesthetists, etc.
- Proliferation of APP employment
  - Physician shortages and patient access needs
  - Cost effective
  - Top 20 Most Requested Searches by Specialty (Merritt Hawkins 2021)
    - NP - #1
    - CRNA - #10
    - PA - #17
- Escalation in productivity-based physician compensation
  - About 70% of employed physicians are compensated under a wRVU productivity-based model (SullivanCotter 2020)

Problem - Overview

Productivity generated by the APP may be attributed to the Physician for compensation determination, even in a compliant billing process

- Many organizations believe if billing regulations are met, compliance with the regulatory definition of personally performed is occurring. This is not necessarily true.
- Billing regulations do not address the potential Stark Law issue under the employment exception, which requires the services to be ***personally performed by the Physician***.
- The Stark Law defines personally performed by describing what is *not* personally performed – “not personally performed or provided by the referring physician if it is performed or provided by another person, including but not limited to, the referring physician’s employees, independent contractors, or group practice members.”

Problem - Overview

- The APP impact to a Physician could be substantial with a highly productive Physician and highly leveraged APP
- Example (real life) impacts to productivity:
  - Orthopedic Surgery ~10% to 20%
  - Neurosurgery ~10% to 20%
  - Gastroenterology ~15% to 25%
  - Interventional Cardiology ~10% to 20%

Billing for APP Services

- Personally-Performed/Independently Billed – The APP provides the service independently
- Incident-to – The APP performs services “incident to” that of a Physician’s clinical treatment plan
- Split-Shared – The APP and Physician jointly perform the services
- Global Surgical Package – The service includes the preoperative, intra-operative, and post-operative services and follow up visits. The APP and Physician jointly perform the services

APP Considerations

- **APP Reduction (Least Utilized)**
  - The net cost (or portion of the cost) is deducted from Physician compensation
  - Net cost includes APP personally-performed professional collection, compensation, benefits, malpractice insurance and an estimate of fully-allocated overhead
- **Physician wRVU Reduction #1**
  - The Physician is paid differently for personally-performed and APP-attributed wRVUs
  - Methodology based on the 15% differential between Physician and APP reimbursement for personally-performed services
  - Inference made is that the difference in reimbursement approximates the value of APP supervision
  - Services provided with the assistance of an APP and attributed to the Physician are compensated at 15% of the Physician's contractual compensation per wRVU
  - The Physician's personally-performed wRVUs are multiplied by 100% of the Physician's contractual compensation per wRVU
  - Methodology relies on an estimate of Physician wRVUs which are which are personally performed by the APP and attributed to the Physician

APP Considerations (continued)

- **Physician wRVU Reduction #2**
  - The Physician is paid the same for each wRVU, but the wRVU total is reduced by a factor for wRVUs attributed to the APP
  - Reduction varies widely by specialty, APP usage
  - Methodology relies on an estimate of Physician wRVUs which are which are personally performed by the APP and attributed to the Physician
  - Requires derivation of estimate
- **Physician Compensation per wRVU Reduction (Most Utilized)**
  - The Physician is paid at 100% of attributed wRVUs, but at a discounted compensation per wRVU value
  - Analysis of methodology relies on an estimate of Physician wRVUs which are which are personally performed by the APP and attributed to the Physician

Other Considerations

- What about APP supervision stipends for Physicians?
  - Use caution – no double-dips!
    - Some consideration of supervisory compensation embedded in wRVUs, compensation per wRVU, etc.
  - Intended to compensate Physician for actual time spent with the APP
    - Reviewing a percentage of APP charts
    - Discussing chart reviews with the APP
- One Physician, multiple APPs
  - The Physician's productivity level is finite
  - Only a modest difference in difference between using one APP or many APPs

Provider Needs Assessments

Needs Assessment Background

- A provider needs assessment (PNA) helps determine the provider complement required in a defined service area by estimating provider needs for a population and determining the appropriate number of providers to meet those needs
- Important component of a hospital or health system's strategic planning process
- Supports compliant provider recruitment activities under applicable federal and state laws and requirements
- Determine the provider complement required in a defined service area by estimating provider supply and demand, by specialty, for a population
- May include consideration of advanced practice providers ("APPs") in the defined service area
- Incorporates both quantitative *and* qualitative analyses

Needs Assessment Assumptions

- Directional analysis intended to inform a health system regarding its relative provider need by specialty
- Results may guide health systems as they determine which provider arrangements are needed and/or which relationships to further pursue.
  - While a specialty may have provider deficits, a PNA does not imply that all specialties with provider deficits should be actively recruited.
  - Resulting surplus does not prohibit the pursuit of a specific recruitment; however, it does warrant careful consideration of additional facts and circumstances in either case.
- Since conducted at a specific point in time, contemplated assumptions (specifically those related to provider supply) are subject to change.
- A PNA is different from a Community Health Needs Assessment ("CHNA") which is required to be completed by tax exempt hospitals under Section 501(r) of the Affordable Care Act.
- Assumptions related to provider demand are based on various approaches including the use of industry accepted physician-to-population ratios.

Key Provider Need Considerations

- Applicable federal and state laws and requirements that should be considered before entering into recruitment arrangements include:
  - **Stark Law Physician Recruitment Exception**: Permits a hospital to remunerate a physician to induce the physician to relocate his/her medical practice to a geographic area served by the hospital in order to become a member of its medical staff if certain conditions are met. Completion of a provider needs assessment using the "geographic service area served by the hospital" assists with compliance.
  - **Non-Physician Practitioner Recruitment Assistance Exception:** Permits hospitals to provide financial assistance to a physician or group to recruit a non-physician practitioner (i.e., APP).
  - **Anti-Kickback Statute (AKS) Physician Recruitment Safe Harbor**: Applicable only in recruitment payments intended to induce a physician to relocate to a designated Health Professional Shortage Area (HPSA).
  - **Internal Revenue Service (IRS)**: Not-for-profit hospitals that are tax-exempt must be cognizant of the fact that recruitment and compensation packages offered could jeopardize an organization's tax-exempt status if they are not reasonable or if they result in inurement or excess private benefit. The IRS provides guidelines for compliance.

Key Provider Need Considerations

- The IRS offers several guidelines on physician recruitment and states that a provider will not be a “permissible recruit” unless there is a community need evidenced by:
  - Physician-to-population ratio that reveals a deficiency in the specialty being recruited
  - Demand for a particular service within the community, as well as a documented lack of availability of the service or especially long wait times to receive the service
  - Federal designation as a HPSA by the Health Resources & Services Administration at the time of recruitment
  - Documented lack of providers serving indigent or Medicaid patients, provided that recruits commit to serving a significant number of these patients[1]

[1] IRS Physician Recruitment Guidelines, October 1994. Please note that while these guidelines are dated, the methods for determining physician need are still considered valid.

COVID-19 Checklist Update

Federal and State Assistance

Considerations

- Paycheck Protection Program
- Families First Coronavirus Response Act
- Medicare Accelerated and Advance Payments
- CARES Act Provider Relief Fund
- FEMA Assistance
- State relief programs

Each of these programs has specific eligibility and performance requirements, including reporting and documentation requirements.

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

HIPAA

Considerations

- HHS has exercised the authority to waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule:
  - The requirements to obtain a patient's agreement to speak with family members or friends involved in the patient's care
  - The requirement to honor a request to opt out of the facility directory
  - The requirement to distribute a notice of privacy practices
  - The patient's right to request privacy restrictions
  - The patient's right to request confidential communications

Action	Ensure a hospital's documented process is in place to demonstrate that certain sharing of protected health information (PHI) outside of the HIPAA Privacy Rule requirements is applied to situations which met required conditions.
Action	Ensure the use of a HIPAA-compliant communication, transmission, and social media solution and application of best practices that protect critical information and safeguard patient privacy.
Action	Thoroughly document and report any breach investigation within 60 days of discovery. Complete documentation and root cause analysis of a breach should also support attempts to prevent, control, and respond to the spread of COVID-19.
Action	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.

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.
- Patient consent is still required for disclosure of SUD treatment records by a Part 2 Program. With a general consent, disclosures and redisclosures may be made consistent with HIPAA for treatment, payment and health care operations.
- CARES Act changes adopts HIPAA fines and penalties in the place of Part 2 enforcement mechanism and prohibits the use of SUD records in civil, criminal, legislative or administrative proceedings without a court order. Further, CARES Act applies the HIPAA breach notification rules.

Action	Develop or update organizational processes to ensure the provisions of the CARES Act for 42 CFR Part 2 SUD information are in place.
Action	Ensure events are appropriately reported and analyzed for future patient safety improvements.

Conditions of Participation for COVID-19 Data Reporting

Considerations

- CMS is requiring hospitals and CAHs to report information in accordance with a frequency, and in a standardized format, as specified by HHS during the PHE for COVID-19.
- CMS states universal reporting by all hospitals and CAHs is and will be an important tool for supporting surveillance of COVID-19 and for future planning to prevent the spread of the virus, especially to those most vulnerable and at risk to its effects.

Action	Facilities must develop and implement a process to collect and report COVID-19 information in accordance with CMS-3401-IFC.

Monitoring Regulatory Guidance

Considerations

- The organization has a process in place to monitor all avenues of regulatory guidance affecting activities during and post-pandemic.

Action	Ensure monitoring for updates, changes and new developments has been effectively assigned, that monitoring continues, and that updates are communicated and evaluated for applicability.
Action	Guidance for other areas subject to compliance implications is also available, including: Swing Beds Interoperability Rule flexibilities Data sharing with state and federal officials. Infection control considerations. Management of elective procedures. Extension of quality and cost report filing deadlines.

How can we HELP?

A national healthcare advisory services firm providing consulting, audit, and tax services