MACRA/MIPS, HIPAA, AND OTHER HEALTHCARE LAWS – SPINNING YOU IN CIRCLES?

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Discussion Points

- MACRA – Effect on Reimbursement:
  - The Quality Payment Program
  - MIPS, APMs, Virtual Groups
  - What to expect going forward

MACRA Overview

- Quality
- Promoting Interoperability
- Improvement Activities
- Cost

There are many changes to MACRA/MIPS, are you ready for those changes?

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Major Provisions

- Eligibility
- Performance Categories & scoring
- Data Submission
- Performance Period & Pay Adjustments

Provision 1: Eligibility

MIPS eligibility
(Participants & Non-Participants)

- Participants Include
  - Physicians (MD/DO and DMD/DDS)
  - Physician's Assistants
  - Nurse Practitioners
  - Clinical Nurse Specialists
  - Certified Registered Nurse Anesthetists
  - Certified Nurse mid-wives
  - Clinical Social Workers

MIPS eligibility
(Participants & Non-Participants)

- Participants Include
  - Physical Therapists
  - Occupational Therapists
  - Speech-language pathologists
  - Audiologists
  - Clinical psychologists, and
  - Registered dietitians

MIPS eligibility
(Participants & Non-Participants)

- Non-Participants Include
  - First year of Medicare Part B participation
  - Below "low volume threshold"
    - Medicare billing charges of less than/equal to $90,000
    - provide care for 200 or fewer Medicare patients in one year, or
    - Furnish 200 or less covered professional services paid under the physician fee schedule.
  - Certain participants in Advanced Alternative Payment Models
  - **DOES NOT APPLY TO HOSPITALS OR FACILITIES**

Provision 11:
Performance Categories & Scoring

Quality 30%

Promoting Interoperability 25%

Improvement Activities 15%

Cost 30%

MIPS
Performance Categories Overview

- Quality
  - Quality measures for 2022 are available in the MACRA 2022 Final Rule
  - Clinicians can still choose the measures on which they'll be evaluated.

MIPS
Performance Categories Overview

- Promoting Interoperability
  - Percentage weight of this may continue decrease as more users adopt EHR

MIPS
Performance Categories Overview

- Improvement Activities
  - Care Coordination
  - Shared Decision Making
  - Safety Checklists
  - Expanding practice access

Improvement Activities – 15%

MIPS
Performance Categories Overview

- Cost Use
  - Compare costs used to treat similar care episodes and clinical condition groups across practices
  - **Can be risk adjusted to reflect external factors**

Provision 11:
Performance Categories & Scoring

Performance Categories

Deep Dive

QUALITY

Quality Performance Category
Selection of 6/200 quality measures

- Full year of quality measure data required
  - One quality measure must continue to be:
    - Outcome Measure OR High Priority Measure

If no Outcome Measure is available for your specialty or practice, then two High Priority Measures are required

2022 MACRA Final Rule removes the end-to-end electronic reporting and high priority/outcome measure bonus points. Next year they will remove the 3-point floor for scoring measures

Quality Performance Category
Selection of 6/200 quality measures

- Different requirements for groups reporting through CMS Web Interface or those in APMs
- May also select specialty-specific set of measures
- May open up additional measures that could be met if reporting as a virtual group.

Quality Performance Category
Key Changes From 2021
Quality Performance Category

- Ability to Opt-In is still an option
- Can now register as a MIPS Value Pathways practice, opening up new measures.
- Category weights have changed
- Year 6 (2022) Weight: 30% of final score

Scoring Methodology for Quality

- Clinicians receive three to ten points on each quality measure based on performance against benchmarks
  - Clinicians must continue to report on a full year of quality data
  - Must meet case volume criteria in order to receive more than three points. (average case volume is 20 cases)

Failure to submit performance data for a measure results in ZERO points for that measure

Scoring for Quality (30% of Final Score)

- Need at least 20 patients that meet the measure in order to meet the following criteria:
  - Meet or exceeds the minimum case volume (has enough data to reliably measure)
  - Meets or exceeds data completeness criteria
  - Has performance greater than 0 percent

Scoring for Quality (30% of Final Score)

- Not all measures will have a benchmark. If there is no benchmark, then a clinician only receives 3 points.

MIPS Scoring for Quality

QUICK TIP: Maximum score cannot exceed 100%

Provision 11:
Performance Categories & Scoring

Performance Categories

Deep Dive

Cost

Cost Category

- There are 20 Cost Measures
- CMS is adding 5 new cost measures this year (2022)
  - 2 procedural measures
    - Melanoma Resection
    - Colon and Rectal Resection
  - 1 acute inpatient measure
    - Sepsis
  - 2 chronic condition measures
    - Diabetes
    - Asthma/Chronic Obstructive Pulmonary Disease [COPD]

Cost Category

- The 5 new episode-based cost measures have the following case minimums (calculated using administrative claims data):
  - Asthma/COPD: 20 episodes
  - Colon and Rectal Resection: 20 episodes
  - Diabetes: 20 episodes
  - Melanoma Resection: 10 episodes
  - Sepsis: 20 episodes

Provision 11:
Performance Categories & Scoring

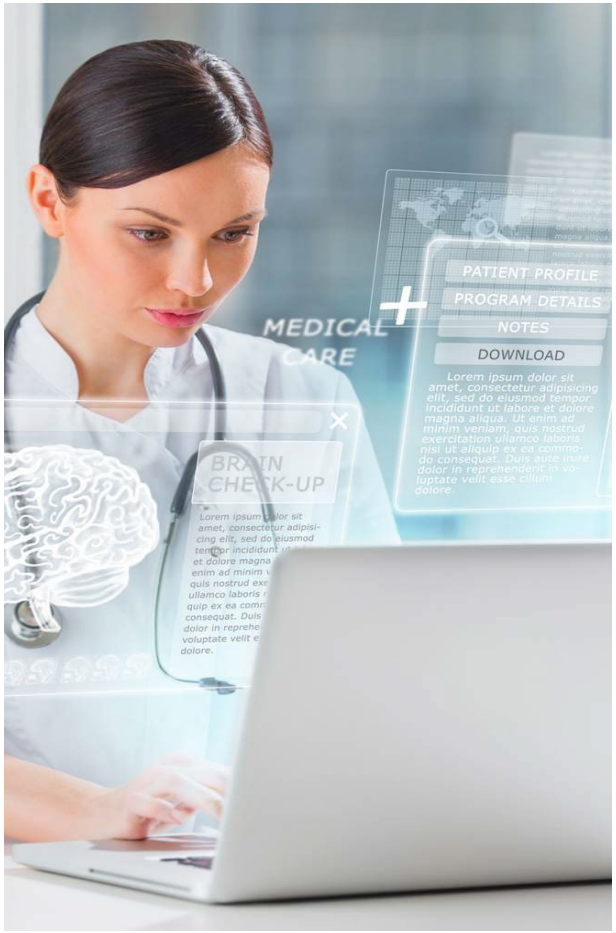
Performance Categories

Deep Dive

PROMOTING INTEROPERABILITY

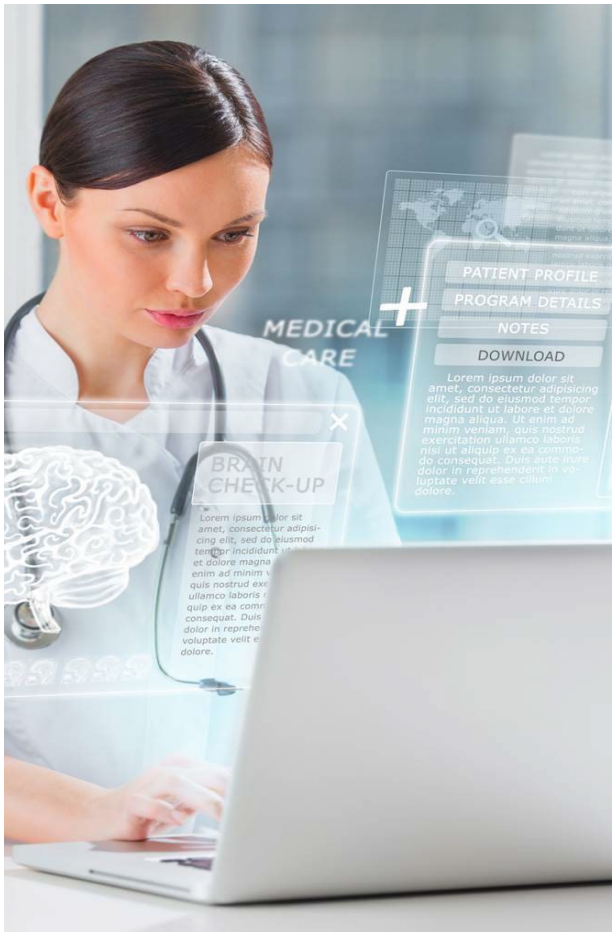
Promoting Interoperability Category

- Key things to remember for PI in 2022 *(year 6 weight: 25%)*
  - 90-day reporting for PI still allowed for individual, group and virtual groups.
  - all physicians/clinicians are still required to use 2015 EHR/EMR edition



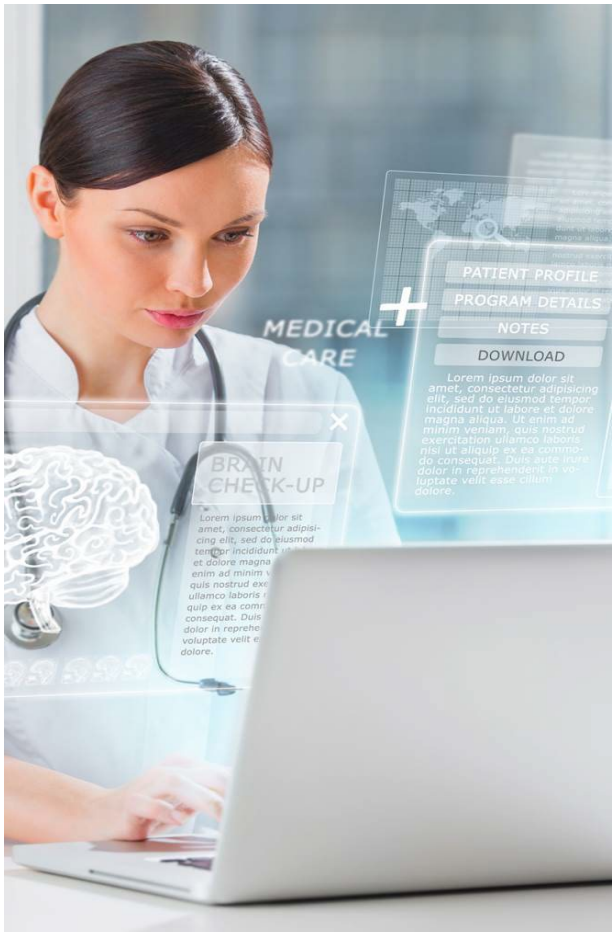
Promoting Interoperability Category

- Applying automatic reweighting to clinical social workers and small practices.
- Revise reporting requirements for the Public Health and Clinical Data Exchange objective to support public health agencies (PHAs) during future health threats and COVID-19 recovery process.
- Add a 4th exclusion for the Electronic Case Reporting measure, available for the 2022 performance period only.



Promoting Interoperability Category

- PI Changes for 2022 (Continued):
- Require MIPS eligible clinicians to attest to conducting an annual assessment of the High-Priority Guide of the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides), beginning with the CY 2022 performance period.
- Modify the Prevention of Information Blocking attestation statements to distinguish this from separate information blocking policies under 21st Century Cures Act Final Rule.



Provision 11:
Performance Categories & Scoring

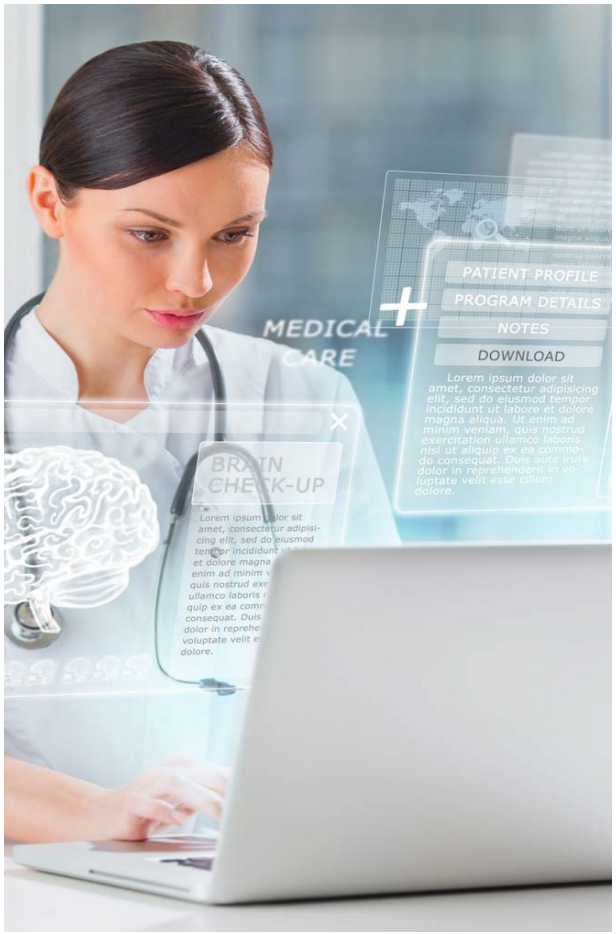
Performance Categories

Deep Dive

IMPROVEMENT ACTIVITIES

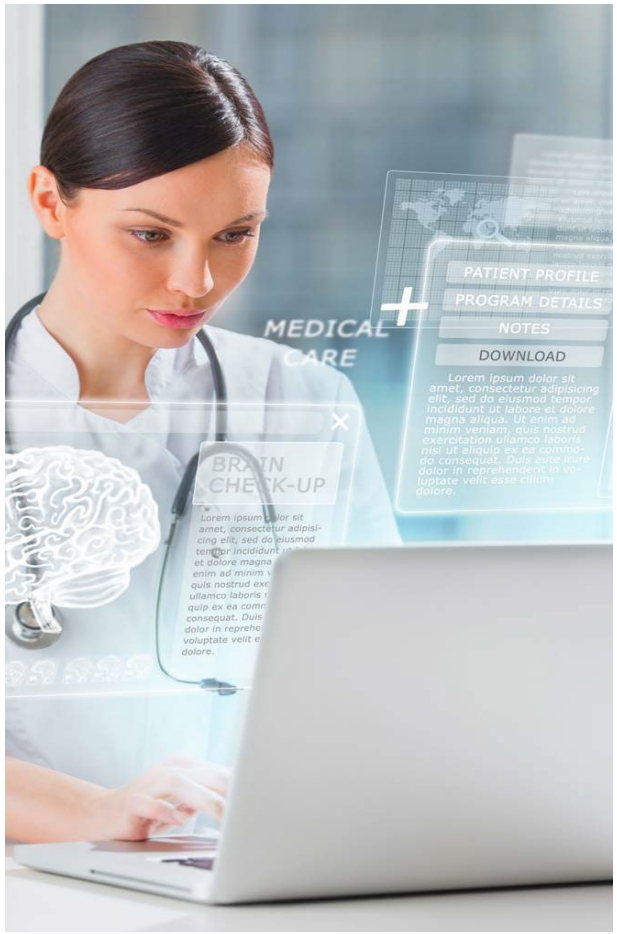
Improvement Activities Category

- Key things to remember for IA in 2022 *(year 6 weight: 15%)*
  - 90-day reporting for IA still allowed for individual, group and virtual groups.
  - Small practices, rural practices, and non-patient facing clinicians only need to do one high weighted, or two medium weighted to reach 40 points.



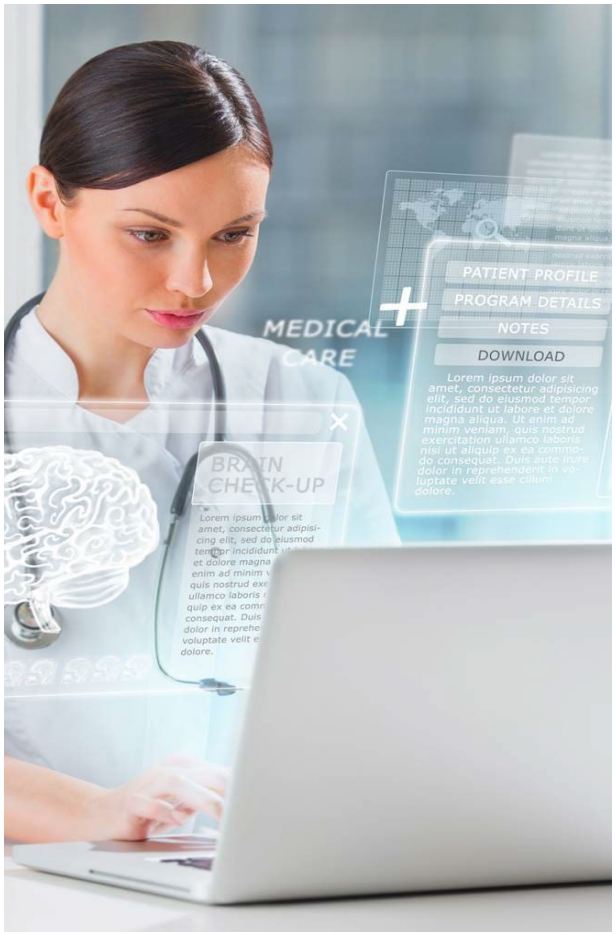
Improvement Activities Category

- Key things to remember for IA in 2022
  (year 6 weight: 15%)
  - CMS is adding 7 new improvement activities, 3 of which are related to promoting health equity.
  - Modifying 15 current improvement activities, 11 of which address health equity.
    - These modifications allow the activities to focus more explicitly on addressing health equity and, in some cases, specifically add requirements to address racial equity.
  - Removing 6 previously adopted improvement activities.



Data Submission

- Key things to remember for data submission in 2022
  - Do not have to use the same submission mechanism to report all categories.
  - Cost will be reported by Administrative claims only



Data Submission
Avoiding Downward Adjustment (2022)

What is required for data submission to avoid downward adjustment?

- Must have a MIPS overall score of 75%, was 60%.
  - Must report on all categories to get 75% or above now.
    - No exceptional performance bonus going forward.

Data Submission
Avoiding Downward Adjustment (2022)

- Quality data required for full year
- Improvement Activities for 90 days
- Promoting Interoperability for 90 days
- The more points you have in these categories, the higher your MIPS score and the better chance for positive Med Part B reimbursement percentage.

Data Submission
Avoiding Downward Adjustment (2022)

- Don't rely solely on EMR/EHR to report MIPS data.
- Data submission must be a team effort.
- Failure to get someone that knows what they are doing can cost tens of thousands of dollars in Medicare Part B revenue.

Calculating the composite Performance Score for MIPS

MIPS

- Weights of each performance category
  - Quality lowered to 30%
  - Promoting Interoperability still 25%
  - Cost now 30%
  - Improvement Activities is still 15%

Calculating the composite Performance Score for MIPS

MIPS

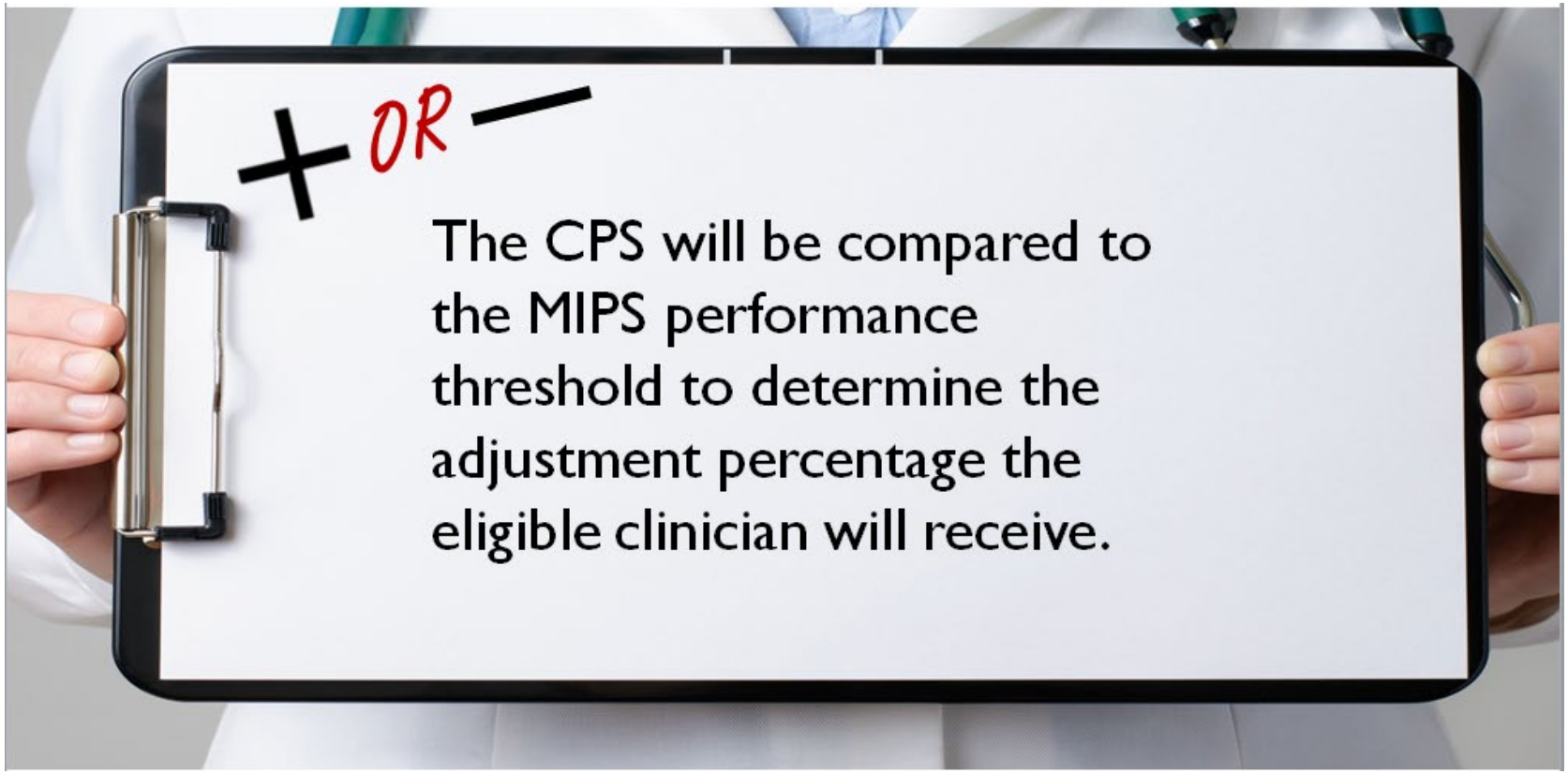
- Exceptional performance bonuses no longer available
- Availability and applicability of measures for different specialties of clinicians still available

Calculating the composite Performance Score for MIPS

MIPS

- Group and virtual group performance scores – individual clinician scores are averaged together to get group score
- Special circumstances for small practices, rural practices, and non-patient facing MIPS eligible clinicians

Calculating the composite Performance Score for MIPS



Calculating the composite Performance Score for MIPS

- 2022 Performance Period
  - January – December
  - First feedback report due in July
- 2023 Reporting and Data Collection
  - Second feedback report due in July
  - Targeted review based on 2022 MIPS performance
- 2024 Adjustments in Effect
  - Could be negative OR positive percentage for doctor/office

Noncompliance with MACRA/MIPS CAN Cost You!

If you fail to fully understand how to completely comply with MACRA/MIPS,

It can cost you:

$$$$, and

Result in lower, or negative, Medicare Part B reimbursement

HIPAA Training: Contingency Plan

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Contingency Plan

- Your plan contains 5 parts:
  - Disaster Recovery
  - Emergency Mode Operation
  - Testing and Revision
  - Critical Data Analysis
  - Evaluation

Disaster Recovery Plan

- Your plan requires a practice to:
  - Review the risk analysis each year to determine potential threats and vulnerabilities, and consequences associated with potential disasters.
  - Identify precautions that can be taken to help reduce risks during and after a disaster.
  - Determine the best way to restore business operations and EHR system recovery after a specific amount of time.

Disaster Recovery Plan

- Your plan requires the practice to:
  - Assign key employees to execute the plan should a disaster occur.
  - Plan for a temporary offsite location with telecommunications and EHR capabilities sufficient to continue to run the practice.
  - Ensure that backed up data used at the temporary location is safeguarded.

Emergency Mode Operation Plan

- Your plan requires the practice to:
  - Identify and arrange for use of an alternate site to perform your practice's EHR and other data functions should those functions be disrupted at the main practice location
  - Ensure that all equipment will be available and working at the primary and any backup sites.

Emergency Mode Operation Plan

- The Plan requires your practice to:
  - Ensure that the temporary location has secure communication capabilities in the event of an emergency.
  - To train all employees on roles and responsibilities during emergency mode operations.

Emergency Mode Operation Plan: Security Officer's role

Emergency Mode Operation Plan: Security Officer's role

- The Security Officer is required to:
  - Determine the extent and seriousness of the emergency
  - Ensure that the practice official responsible for declaring an emergency does so.
  - Notify emergency team (practice) and set up meeting at temporary facility if main practice location is inaccessible, or inoperable, or both.

Emergency Mode Operation Plan: Security Officer's role

- The Security Officer is required to:
  - Inform patients that may be affected by expected duration of the emergency (for example, 24 – 48 hours, or less) that emergency operations have been initiated.
  - Determine if there is additional equipment and/or supplies that are necessary.

Emergency Mode Operation Plan: Security Officer's role

- The Security Officer is required to:
  - Notify EHR system and practice management.
  - Begin shifting from one practice location to the temporary one.
  - Document all actions taken before and during execution of the emergency mode operation plan.

Testing and Revision of a Contingency Plan

- Your Security Official is responsible for:
  - Documenting in writing actions observed during testing of the contingency plan, especially:
    - Successes,
    - Responses
    - Response time, and
    - Weaknesses

Testing and Revision of a Contingency Plan

- Your Security Official is responsible for:
  - Making any necessary modifications to the contingency plan after testing, if necessary, and
  - Conduct any retraining on the contingency plan, if necessary.

Application and Critical Data Analysis

- Using the Risk Analysis data:
  - Establish processes for assessing vulnerabilities and threats
  - Prioritize steps to backup data, recover data, and using data during an emergency

HIPAA TRAINING:

Permissible Disclosures
(Family, Friends, Disaster Relief)
Marketing
Sign-in sheets

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Permissible Disclosures: Disclosures to Family/Friends/Disaster Relief

- The practice may disclose protected health information if:
  - the patient is unable to agree to or prohibit use or disclosure (this should be in very rare circumstances), or
  - if the patient is incapacitated and the disclosure is in his/her best interest.

Permissible Disclosures: Disclosures to Family/Friends/Disaster Relief

- The Practice may also use or disclose patient information with a family member, or friend, if doing so, in the doctor's professional judgement, would be necessary.
- The Practice may also use or disclose patient information with a family member or friend of the patient, if the patient is either incapacitated, or it is felt by a medical professional that the patient would not object.
  - DO NOT ASSUME the patient would not object!

Permissible Disclosures: Disclosures to Family/Friends/Disaster Relief

- If the patient is incapacitated:
  - If disclosure would not be in the best interest of the patient, **NO DISCLOSURE MAY TAKE PLACE**.
    - Example: if you believe a minor patient has been abused, neglected, or the subject of domestic abuse, by his/her parent or guardian, you should **NEVER** disclose any medical information with the parent or guardian.
      - You can, however, **DISCLOSE TO POLICE OR OTHER AUTHORITIES** your suspicions of patient abuse by the parent or guardian. No authorization, or permission, from the parent, guardian, or patient is required in this instance.

SIGN-IN SHEETS

- Sign-in Sheets and HIPAA are like oil and water.
  - In some situations, useful but may not be worth the effort.
- A practice may use a sign-in sheet for patients when they arrive for visits.
  - There are different types of sign-in sheets and different requirements depending on which type you use.

SIGN-IN SHEETS

- Sign-in Sheets:
  - Different types of sign-in sheets and the requirements to use them to comply with HIPAA:
    - Removable name stickers:
      - If the sign-in sheet allows you to remove the name from the sheet after the patient signs in, then the sign-in sheet **can be** left out for all patients to see once the patient's name has been removed.

SIGN-IN SHEETS

- Sign-in Sheets:
  - Different types of sign-in sheets, and the requirements to use them, to comply with HIPAA:
    - Other Patient Sign-in Sheets:
      - Any other type patient sign-in sheets, and HIPAA requirements, would be based on how the list is developed - a fact specific situation.

MEDICARE FRAUD, WASTE, & ABUSE LAWS

- The FCA, AKS, Physician Self-Referral Law (Stark Law), Criminal Health Care Fraud Statue, Social Security Act, which includes the Exclusion Statute, and Civil Monetary Penalty Law, are the main laws that address Medicare fraud & abuse and specify the criminal, civil, and administrative penalties the government imposes on those committing fraud & abuse.
  - Violations may result in:
    - Medicare-paid claims recoupment
    - Civil Monetary Penalties (CMPs)
    - Exclusion from Federal health care programs participation
    - Criminal and civil liability
  - These laws prohibit Medicare Part C and Part D and Medicaid fraud & abuse.

FEDERAL FALSE CLAIMS ACT (FCA)

- The FCA protects the Federal government from being overcharged or sold substandard goods or services.
- The FCA imposes civil liability on any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the Federal government.
  - The terms "knowing" and "knowingly" mean a person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information related to the claim.
- There is also a criminal FCA. Criminal penalties for submitting false claims may include prison, fines, or both.

- **Example:** A physician knowingly submits claims to Medicare for medical services not provided or for a higher level of medical services than provided.

FEDERAL FALSE CLAIMS ACT (FCA)

- Examples:
  - A provider who submits a bill to Medicare or Medicaid for services that were not rendered
  - A provider who obtains interim payments from Medicare throughout the year, and then knowingly files a false cost report at the end of the year in order to avoid making a refund to the Medicare program
  - Submission of false information about services performed or charges for services performed
  - Inserting a diagnosis code not obtained from a physician or other authorized individual
  - Misrepresenting the services performed (for example, up-coding to increase reimbursement)
  - Submission of claims for services ordered by a provider who has been excluded from participating in Medicare, Medicaid and other federally funded health care programs

ANTI-KICKBACK STATUTE

- The AKS makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration directly or indirectly to induce or reward referrals of items or services reimbursable by a federal health care program.
  - Remuneration includes anything of value such as cash, free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultations.
  - Criminal penalties and administrative sanctions for violating the AKS may include fines, imprisonment, and exclusion from participating in Federal health care programs.
- The Code of Federal Regulations (CFR) sets the safe harbor regulations and describes various payments and business practices that may satisfy regulatory requirements and may not violate AKS.
- **Example**: A provider gets cash or below-fair-market-value rent for medical office space in exchange for referrals.

ANTI-KICKBACK STATUTE

- An arrangement will be deemed to not violate the Anti-Kickback Statute if it fully complies with the terms of a safe harbor issued by the Office of the Inspector General (OIG). Arrangements that do not fit within a safe harbor and thus do not qualify for automatic protection may or may not violate the Anti-Kickback Statute, depending on the facts.

ANTI-KICKBACK STATUTE

- Examples:
  - A provider who has a general policy and practice of routinely waiving member copayments and deductibles to induce Medicare and/or Medicaid beneficiaries to receive services from the provider
  - Payments to a Medicare provider by a supplier to induce the purchase of Part B products from that supplier
  - Other incentives to a provider or contractor, such as a pharmacy that induces Medicare beneficiaries to enroll in a particular Medicare Advantage or Part D plan

PHYSICIAN SELF-REFERRAL LAW (STARK)

- The Physician Self-Referral Law (Stark Law) prohibits a physician from referring certain "designated health services" (for example, clinical laboratory services, physical therapy, and home health services), payable by Medicare or Medicaid, to an entity where the physician (or an immediate family member) has an ownership/investment interest or has a compensation arrangement, unless an exception applies.
  - Penalties for physicians who violate the Stark Law include, fines, repayment of claims, and potential exclusion from participation in Federal health care programs.
  - **Example**: A provider refers a patient for a designated health service to a clinic where the physician (or an immediate family member) has an investment interest.

CRIMINAL HEALTH CARE FRAUD STATUTE

- The Criminal Health Care Fraud Statute prohibits knowingly or willfully executing, or attempting to execute, a scheme or lie about the delivery of, or payment for, health care benefits, items, or services to either:
  - Defraud any health care benefit program
  - Get (by means of false or fraudulent pretenses, representations, or promises) the money or property owned by, or under the custody or control of, a health care benefit program
- Penalties for violating the Criminal Health Care Fraud Statute may include fines, prison or both.

BENEFICIARY INDUCEMENT LAW

- Prohibits offering a remuneration that a person knows or should know is likely to influence a beneficiary/member to select a particular provider, practitioner, or supplier; and
- Creates civil liabilities with monetary penalties of up to $10,000 for each wrongful act.
- Examples:
  - A provider who has a general policy and practice of routinely waiving member copayments and deductibles to induce Medicare and/or Medicaid beneficiaries to receive services from the provider
  - Providers who give Medicaid & Medicare beneficiaries "gifts" to influence the beneficiaries' decision to select the provider

WHISTLEBLOWER PROTECTION ACT

- To encourage individuals to come forward and report misconduct involving false claims, the False Claims Act includes a "qui tam" or whistleblower provision. This provision essentially allows any person with actual knowledge of false claims activity to file a lawsuit on behalf of the U.S. government.
- Under federal law, the whistleblower may be awarded a portion of the funds recovered by the government, typically between 15 and 30 percent. The whistleblower also may be entitled to reasonable expenses, including attorney's fees and costs for bringing the lawsuit.
- In addition to a financial award, the False Claims Act entitles whistleblowers to additional relief, including employment reinstatement, back pay, and any other compensation arising from employer retaliatory conduct against a whistleblower for filing an action under the False Claims Act or committing other lawful acts, such as investigating a false claim, providing testimony, or assisting in a False Claims Act action.

WHISTLEBLOWER PROTECTION ACT

- The False Claims Act includes specific provisions to protect whistleblowers from retaliation by their employers. Any employee who initiates or assists with an FCA case is protected from discharge, demotion, suspension, threats, harassment and discrimination in the terms and conditions of his or her employment.
- THERE'S A CATCH:
  - A person who brings a qui tam action that a court later finds was frivolous may be liable for fines, attorney fees and other expenses.

OTHER RELEVANT FEDERAL FWA LAWS

- **Civil Monetary Penalties Law**
  - The federal Civil Monetary Penalties Law covers an array of fraudulent and abusive activities and is similar to the False Claims Act. Violations of the law may result in penalties between $10,000 and $50,000 and up to three times the amount unlawfully claimed.
- **Exclusion Statute**
  - The Exclusion Statute requires the U.S. Department of Health & Human Services (HHS) Office of Inspector General (OIG) to exclude health care providers and suppliers convicted of certain offenses from participating in Federal health care programs.

EXCLUSION STATUTE

- **Exclusion Statute: Referrals**
  - Excluded providers may not participate in Federal health care programs for a designated period but may refer a patient to a non-excluded provider if the excluded provider does not furnish, order, or prescribe services for the referred patient.
- **Mandatory Exclusion**
  - For certain offenses, the OIG **must** impose an exclusion. Mandatory exclusions stay in effect for a minimum of 5 years; however, aggravating factors may lead to an even longer or permanent exclusion. Providers and suppliers face mandatory exclusions of these offenses:
    - Medicare or Medicaid fraud and criminal offenses related to the delivery of items or services under a Federal or State health care program;
    - Criminal offenses related to patient abuse or neglect;
    - Felony convictions for other health care-related fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct connected to the delivery of a health care item or service; and
    - Felony convictions for unlawful manufacture, distribution, prescription, or dispensing controlled substances.

EXCLUSION STATUTE

- **Permissive Exclusion**
  - The OIG may issue permissive exclusions, that vary in length, for various actions, such as:
    - Misdemeanor health care fraud convictions other than Medicare or Medicaid fraud; and
    - Misdemeanor convictions for unlawfully manufacturing, distributing, prescribing, or dispensing controlled substances; and
    - Revocation, suspension, or health care license surrender for reasons of professional competence, professional performance, or financial integrity; and
    - Providing unnecessary or substandard service; and
    - Convictions for obstructing an investigation or audit; and
    - Other situations
- **OIG List of Excluded Individuals/Entities**
  - Providers and contracting entities must check the program exclusion status of individuals and entities in the List of Excluded Individuals/Entities before entering employment or contractual relationships.
    - Health care providers that knowingly hire an excluded party are subject to potential FCA liability and CMPs. Medicare will not pay for services by an excluded party, with certain exceptions.

EXCLUSION STATUTE

- **Exclusion: Reinstatement**
  - Not automatic
    - Must apply for reinstatement and get approval from the OIG that they granted reinstatement.
    - If reinstatement is denied by OIG, the excluded party is eligible to re-apply after 1 year.

RECORD RETENTION REQUIREMENTS

- **Providers must maintain service, prescription, claim and billing records for 10 years.**
- **Records are subject to CMS or contractor audit**
- **These requirements of record retention are different than HIPAA's requirements for retention of medical records.**

COMPLIANCE PLAN

- HHS' Office of the Inspector General has developed compliance plan guidance for several different health care provider types. These guidelines can be accessed at: http://oig.hhs.gov/fraud/complianceguidance.asp.
- In general, **each compliance plan should contain the following elements:**
  - 1. Written policies and procedures
  - 2. Designation of a compliance officer and a compliance committee
  - 3. Conducting effective training and education
  - 4. Developing effective lines of communication
  - 5. Auditing and monitoring
  - 6. Enforcement through publicized disciplinary guidelines and policies dealing with ineligible persons
  - 7. Responding to detected offenses, developing corrective action initiatives and reporting to government authorities
  - 8. Whistleblower protection and non-retaliation policy

WHAT TO DO IF YOU SUSPECT PROBLEMATIC RELATIONSHIPS OR INAPPROPRIATE BILLING:

- Stop submitting problematic bills
- Seek legal counsel
- Determine money collected in error from patients and from Federal health care programs and report and return refunds
- Cease involvement in a problematic investment
- Get out of the problematic relationship(s)
- Consider self-disclosing the issues

ADDITIONAL INFORMATION

- **CMS:** http://www.cms.hhs.gov/
- **HHS/OIG:** http://oig.hhs.gov
- **CMS Prescription Drug Benefit Manual:** https://www.cms.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf
- **CMS Medicaid Integrity:** http://www.cms.gov/MedicaidIntegrityProgram/
- **DEA Drug Diversion:** http://www.deadiversion.usdoj.gov/

QUESTIONS?