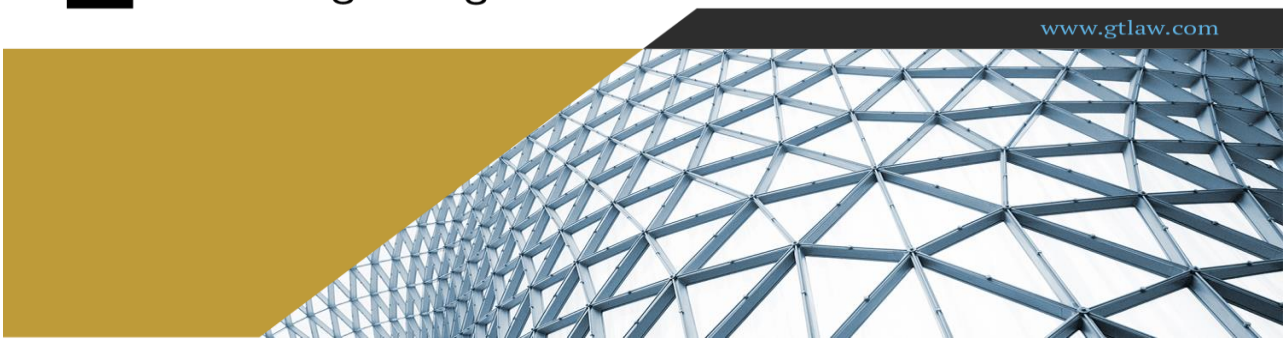
GT GreenbergTraurig

www.gtlaw.com



New York Regional Health Care Compliance Conference (HCCA)

Hot Topics in Compliance

MAY 8, 2020

Whitney Magee Phelps | 518.225.9987

1

2020 Top Compliance Issues

- Federal
  - Physician Self-Referral law (Stark)
  - Anti-Kickback Safe Harbors (AKS) and Civil Monetary Penalties (CMPs)
  - Federal disclosure rules
- New York State
  - OMIG Work Plan
  - NYS Sexual Harassment Policy and training
  - 21st Century Cures Act (changes to Medicaid enrollment)

2

2020 Top Compliance Issues

- NYS Budget and Medicaid Redesign II (MRT II)
  - Administrative Denials
  - Standardized Data Set
  - Program Integrity and Compliance
  - Value-Based Payment
  - Behavioral Health Parity Compliance
  - MLTC Initiatives
  - Consumer Protections
- COVID-19

Federal Compliance

HHS's Regulatory Sprint to Coordinated Care - identified regulatory requirements that impede coordinated care in order to accelerate the transition to a value-based health care system

- Specifically, RFI – June 2018 - asked for feedback on modifications to:
  - Stark regulations,
  - Safe harbors to AKS and CMPs, and
  - Revisions to HIPAA
- October 9, 2019 OIG and CMS released proposed regulations relating to Stark and AKS/CMPs and comments were due December 2019
- Guiding principles:
  - Allow for beneficial innovation in health care delivery
  - Provide safe harbors and exceptions that that reflect up-to-date understandings in medicine, science and technology; and
  - To be useful for a range entities engaged in the coordination and management of care

Stark Law

- In general, a physician cannot refer a patient to any entity with which he or she (or a family member) has a financial relationship
- Initially drafted to combat incentives for overutilization of services caused by patient referrals where the physician has a financial relationship
- Proposed regulations create exceptions to bolster physicians ability to engage in value-based arrangements (VBAs) to improve quality, produce efficiencies and reduce costs
- In theory, overutilization concerns are reduced with VBP and instead need to think about incentives around underutilization or withholding medically necessary services
  - Payment under VBP is based on quality and not volume

Stark Law – Proposed Changes

- Definitional changes to clarify which activities and entities qualify for the value-based arrangement exceptions (e.g., value-based enterprise, value-based arrangement, value-based activity, VBE participant, target budget)
- Exceptions
  - Full risk – prospective capitated payments based on predetermined budget
  - Meaningful downside risk – no less than 25% of provider's remuneration is at risk if specified benchmarks are not met
  - Upside only arrangement
  - Indirect compensation – not a direct transaction between plan and provider
  - Price transparency

Stark Law – Proposed Changes

- Changes to terminology
  - Commercially reasonable compensation
    - Furthers a legitimate purpose, makes commercial sense and the terms and conditions are similar for the type and size of the entities
  - Compensation must be fair market value – arm's-length transaction under like circumstances, of assets and services, consistent with general market value for the transaction
  - Clarifies when compensation is deemed to be based on volume or value of referrals
    - To be considered based on a mathematical formula that includes referrals and the compensation amount correlates with the volume of referrals
  - Changes to Group Practice exception to allow for distribution of profit shares, productivity bonuses and revenue associated with participation in VBE

Anti-Kickback

- Makes it illegal to accept bribes or other remuneration in exchange for generating business through Medicare, Medicaid or other federal health care programs
- Proposed rule creates several new safe harbor exceptions and modifies others
- Safe harbor regulation describes various arrangements (payment and business practices) that although potentially implicate AKS, are not treated as an offense if all of the elements are met

Safe Harbors for Anti-kickback and CMPs

- VBA
  - Three new safe harbors for remuneration (in-kind and monetary) exchanged for participation in VBA to foster care coordination
  - Coordination arrangement, full risk and substantial downside risk
- Patient Engagement
  - A new safe harbor for tools and supports furnished under patient engagement to improve outcomes and efficiencies (n/a for Pharma, labs, DME)
- Donations of cybersecurity and technology
- Amend personal service and management safe harbor to provide flexibility for outcome-based payments and part-time arrangements
- New safe harbors will also be covered exceptions to the beneficiary inducement definition for remuneration

CMS Anti-Fraud Measurers

All providers must disclose any current or prior (last 5 years) affiliations or any "disclosable event" of an organization, its owners or managing employees

- Affiliation Includes
  - 5% or more direct or indirect ownership in another organization
  - A general or limited interest in another organization
  - An interest that equates to the "exercise of operational or managerial control over, or directly or indirectly, conducts the day-to-day operations of another entity"
  - An officer or director of an entity or any reassignment
- Disclosable Event Includes:
  - Uncollectable debt to CMS
  - Current or previous payment suspension from a federal health care program
  - Current or previous exclusion from a federal health care program, or
  - Previous denial, Revocation, or termination of Medicare, Medicaid or CHP billing privileges

CMS Anti-Fraud Measurers

- Upon such a disclosure, CMS can deny or revoke enrollment if it determines the affiliation "poses an undue risk of fraud, waste and abuse"
- Failure "to fully and completely disclose" information that is known or should have been known" can result in denial or revocation of Medicaid enrollment
- CMS also has more authority and discretion to deny or revoke Medicare enrollment
  - Pattern or practice of abusive ordering or billing
  - Billing for services from non-compliant locations
  - Outstanding debt to CMS

  Bar on re-enrollment was also extended from 3 years to up to 10 years and providers excluded for a second time can lose privileges for up to 20 years

State Compliance

OMIG Work Plan 2019-2020

- Strategic Plan with 3 Goals
  - Provider and MCO compliance
  - Safeguarding Medicaid resources by actively employing best practices and state-of the-art tools to address fraud, waste and abuse
  - Focus on recipient safety and promoting high quality patient care through program integrity initiatives

Goal 1 – Provider and MCO Compliance

- OMIG will post on its website contractual obligations that will be subject to review, including benchmarks
- Audit of network providers for accuracy of encounter claim submissions and that provider records are in regulatory and contractual compliance
- Strengthen MCO referral process through OMIG Designated MCO Liaisons that discusses fraud, waste and abuse referrals and trends

Goal 2 – Medicaid Resources

- OMIG will conduct audits of FFS providers to ensure federal waiver requirements are being met and specifically, OASAS and OMH providers
- Provide oversight and conduct reviews of Medicaid EHR Incentive program requirements
- OMIG and DOH will partner with a data analytics firm to recover payments made in error on behalf of incarcerated or deceased recipient
- Review duplicate Medicare-Medicaid crossover payments

Goal 3 – Safety and Quality

- Prescription monitoring to combat opioid abuse
- Utilization alerts
- Recipient restriction program
- Physician prescribing excessive amounts of controlled substances and unnecessary services

NYS Sexual Harassment Prevention Training

- New York State Sexual Harassment Prevention Training required for all not-for-profit organizations
- On or before October 9, 2019, all New York employees are to be training in sexual harassment prevention and annually thereafter

Medicaid Provider Enrollment

- 21st Century Cures Act (Section 5006) requires a state Medicaid agency to publish a Medicaid fee for service (FFS) provider directory https:Health.data.ny.gov
- Directory will allow Medicaid and Child Health Insurance Program plans to confirm Medicaid FFS / MCO enrollment and for consumers to search for providers
- Medicaid Enrolled Provider Listing (now updated weekly and provides next anticipated revalidation date)

State Budget and MRT II

Prior to COVID-19, Governor Cuomo formed the MRT II Team in February 2020 to restore financial sustainability to the Medicaid program ($2.5mm target savings) and find program initiatives that would advance DOH's core healthcare strategies and policy objectives.

- Recommendations were submitted to the Governor and many advanced through the budget.
- We will discuss the compliance related initiatives

Administrative Denials
PHL 4406 c

- Plans cannot deny payment to general hospitals for medically necessary inpatient, observation services and emergency department services solely based on non-compliance with certain plan administrative requirements
- Allows general hospital and plan to agree to certain administrative requirements with some limitations
- Limitations:
  - If requiring timely notification, must allow reasonable
  - Extension for weekends and holidays;
  - Reduction in payment for administrative non compliance;
  - Cannot exceed 7.5%; and
  - reduction in payment shall not be imposed if the patient's coverage could not be determined by the hospital after reasonable efforts

Administrative Denials
PHL 4406 c

Exceptions:

- Denials for fraud or intentional misrepresentation of patient diagnosis or services provided or abusive billing
- When required by a government program
- Duplicate claim
- There is no participating provider agreement between hospital and plan (except for medically necessary inpatient services resulting from emergency admission)
- During last 12 months, hospital has repeatedly and systemically failed to seek prior authorization where prior authorization was required
- A request for preauthorization was denied by the health care plan prior to delivery of the service

Standardized Medicaid Managed Care Prior Authorization Data Set

- Administrative action to reduce the number of unnecessary service request denials and subsequent appeals filed due to Provider submission of inadequate/incomplete data to MCO's for Prior Authorizations
- Data set will allow MCOs to approve more service requests in the first instance and reduce MCO and provider administrative burden and improve service delivery
- DOH will convene Workgroup of subject matter experts/stakeholders to develop/implement the standard data set, which may include:
  - diagnosis,
  - provider identifiers,
  - procedure codes, and
  - enrollee clinical information

Program Integrity Implementation

- Imposes monetary penalties upon providers who fail to adopt and implement a compliance program. **NOW REQUIRED FOR EVERY MEDICAID PROVIDER**.
  - Compliance Reviews on or after January 1, 2021.
  - Condition of payment
- Managed care providers, including managed long-term care plans, are subject to the Provider Compliance Program provisions
- Imposes penalties for the submission of misstated cost reports (submitted on or after January 1, 2014). Provides Medicaid fraud, waste and abuse prevention requirements for managed care providers.
- Home Care Service workers are required to obtain an individual unique identified from the State

Immediately, full force and effect 4/1/2020

Program Integrity Implementation

- Mandates that if a person has received an overpayment under the Medicaid program, the person shall report and return the overpayment to the Department, and notify the Medicaid Inspector General in writing of the reason for the overpayment.
- An overpayment shall be returned within 60 days from when it was identified, or the date of any corresponding cost report is due. The Medicaid Inspector General may toll the deadline for returning overpayments under certain circumstances.
- Creates a voluntary self-disclosure program.

Immediately, full force and effect 4/1/2020

Program Integrity Implementation

- For Medicaid, require MCOs and MLTCs to have fraud and abuse prevention plans, which includes SIUs, if more than 1,000 enrollees and update standards/requirements
- Monetary penalties for plans that submit cost reports containing misstatements of fact
- Penalties on MCOs for not submitting encounter data

Program Integrity Implementation

- Monetary penalties may be imposed if:
  - i) a person orders, prescribes or furnishes care, services or supplies that are medically improper,
  - ii) a person fails to grant timely access to facilities and records, upon reasonable notice, to the Medicaid Inspector General, the Medicaid fraud control unit of the AG's Office, or DOH for the purpose of audits, investigations, reviews, or other statutory functions;
  - iii) a person knew or should have known that an overpayment has been identified and does not report, return and explain the overpayment; and
  - iv) such person contracts or employs a suspended or excluded individual or entity.

  Penalties may not exceed $10,000 per item or service (up to $30,000 for repeat penalties within five years), and up to $15,000 for each day a person fails to grant timely access under (ii).

Value Based Payment

- Institutes a penalty to be applied to MCO premiums in cases where MCOs do not meet certain quality measure thresholds. Quality measurement for the purposes of this penalty will utilize the QARR framework.
- Explore opportunities to:
  - align payments for maternity and newborn services to improve maternity outcomes;
  - implement more refined behavioral health/substance use disorder VBP arrangements which establish robust integrated care models in variety of settings;
  - establish data and information sharing standards to support timely, accurate, complete and bi-directional sharing of data and information between MCOs and providers to support VBP arrangements; and,
  - strengthen approaches to using member incentives through creation of guiding principles and quality outcomes more aligned with the application of member incentives.

Behavioral Health Parity Compliance

- Creation of Behavioral Health Parity Compliance Fund
  - Funded through fines to MCOs and insurers for failure to adhere to mental health and substance use disorder coverage in a manner consistent with state and federal law
  - Funds used to create ombudsman program and other initiatives to support parity implementation and enforcement
- Mandate DFS/DOH rulemaking regarding behavioral health parity by October 1, 2020, such that the Behavioral Health Parity Compliance Fund was created

MLTC Initiatives

- 2 year moratorium on new MLTCs or expansions
- DOH to assess public need for plans not integrated with an affiliated Medicare plan
- DOH to develop process to conduct winddown and eliminate plans to coincide with end of moratorium period
- Annual cap on MLTC's total enrollment enforced through 3% premium withhold

Effective 4/1/2020

MLTC Initiatives

- Eligibility for MLTC – assessed to need more than 120 days of continuous community based long-term care services and
  - limited or greater assistance with 2 activities of daily living (ADL) or
  - Alzheimer's or dementia assessed to require supervision or greater assistance with 1 ADL
- Eligibility Criteria for Personal Care Services (PCS) and Consumer Directed Personal Assistance (CDPAS) Program
  - Assessed to need more than limited or greater assistance with 2 activities of daily living (ADL)
  - Alzheimer's or dementia assessed to require supervision or greater assistance with 1 ADL

  October 1, 2020 (not apply to anyone enrolled prior to 10/1/2020)

MLTC Initiatives

To ensure consistency in how assessments are completed, responsibility for conducting CHAs will be transferred to an Independent Assessor (IA)

- IA will conduct CHA assessments and re-assessments (Initially, the current Conflict Free Evaluation and Enrollment Center (CFEEC) contract with the State's enrollment broker will conduct the responsibilities of the IA)
- CHAs will be done annually (instead of every six months)
- The Department will change physician ordering practices by establishing a panel(s) of clinical professionals to provide independent physician's authorizations/orders for personal care services, including those provided through the Consumer Directed Personal Assistance Program (CDPAP)
- The panel will use a clear set of protocols and standards to determine if members seeking to be in CDPAP are capable of self directing, either independently or with their consumer designated representatives
  - Enhanced UR process by an independent assessor to ensure any individual needing more than 12 hours/day of PCA/CDPAP is safe to remain in the community

Effective October 1, 2020

MLTC Initiatives

- Implement uniform tasking tool to determine service utilization (number of hours of PCA/CDPAP needed/day)
- Implementation of Electronic Visit Verification (EVV) as required by 21st Century Cures Act
  - Choice model
  - Must be used for all PCA, home health aide and CDPAP services

Licensed Home Care Service Agency (LHCSA) Value and Efficiencies

- Currently, there are over 1,400 LHCSAs that are licensed to furnish personal care, nursing, occupational therapy, and/or speech therapy services in New York State
- To promote quality, value and efficiencies among LCHCSAs, the budget authorizes the Department to issue a request for proposals to create efficiencies to qualify a sufficient number of licensed home care services agencies (LHCSAs) to furnish personal care services in Medicaid fee for service or to managed care plans
- LHCSAs will be evaluated on their adherence to technical requirements, including the ability to perform LHCSA services, past performance history, capacity to serve beneficiaries in the designated services areas, and their administrative costs/efficiencies in delivering LHCSA services
- Expected contracting date July 1, 2021

Health Related Consumer Protections

- Independent dispute resolution process expanded to include inpatient professional services following an ER visit
- Allows assignment of benefits for ER services, including any inpatient admission following an emergency visit and requires consumers held harmless and pay OON providers directly for services and limits billing of patients to cost sharing amounts only
- Statute of limitations for medical debt collection is shortened to 3 years (from 6 yrs)

COVID-19 – PPP and SBA Loans

- Borrowers must certify in good faith that their PPP loan request is necessary
- Review certification careful and be sure you can represent that “the current economic uncertainty makes this loan request necessary to support the ongoing operations of the applicant”
- Good faith, current business activity , and ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business.
- Loan over $2mm will be subject to review and audit by SBA and Treasurer (in addition to other loans as appropriate)
- Recommend:
  - Board or management decision authorizing process for approval of the initial loan application (minutes, resolutions)
  - Financial projections assessing operational need
  - Financial position pre-loan and liquidity needs
  - Alternative source of funding and capital

COVID-19 – Expected Enforcement

- Highly Decentralized Investigations
  - Multiple government entities authorized to pursue civil and criminal false claims, fraud, antitrust, federal contract violations, state consumer protections
- Multiple Starting Points for Enforcements
  - Whistleblowers, Consumer, Employment, Contracts, Media, Congress

COVID-19 – What to do Now

- Consider and Document
  - If something is really profitable because of the crisis, consider and document why it's a good idea
  - If you have accepted government benefits, document rationale or facts demonstrating qualifications
- Involve Compliance Function in More Company Decisions
- Assume there will be review, audit, and enforcement of anything that creates profit or involves receiving government benefits
- Use "Washington Post" test for communications and crisis-based decisions
  - Being technically or legally "correct" won't stop investigations and enforcement actions

