2022 HEALTHCARE UPDATE: FEDERAL & STATE

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OVERVIEW: NEW FEDERAL REGULATIONS

- Stark Law
  - Changes to exceptions took effect January 1, 2022
  - New rules for group practices, profits from in-office ancillary services, and productivity bonuses.
- Anti-Kickback Statute
  - Delayed changes to Safe Harbors within 42 C.F.R. § 1001.952
  - Affects discounts to certain prescription medications

OVERVIEW: NEVADA HEALTHCARE HOT TOPICS

- Legislative Update: 81st (2021) Session
  - Behavioral Health
  - Pharmacy & Prescription Drugs
  - Other Health Care & Provider-Related Legislation
  - The "Public Option" Legislation
  - Implementing Regulations: 2022-2023 Administrative Process

OVERVIEW: THE 2021 SESSION…AND BEYOND

- 2021 Legislative Session Recap
  - First "virtual legislative session" due to COVID-19 restrictions
  - 557 bills total passed and signed into law
  - 4 Vetoed bills, including SB 391 (revising provisions relating to Medicaid benefits for teledentistry)
  - During Interim Period (2022-2023), enacted legislation will be implemented by proposed agency regulations and revisions to Nevada Administrative Code (NAC)

STARK LAW: GENERALLY

- Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, *unless an exception applies*.
- Strict liability– no proof of intent is required to establish liability
- Purpose: referrals based on best interest of patients, to avoid self-referral, overutilization, fraud and abuse.
- 42 USC § 1395nn; 42 CFR §411.350 – §411-389

STARK EXCEPTIONS - COMPENSATION

- Employment
- Personal Services contracts
- Fair market value
- Space or equipment leases
- Timeshare arrangements
- Recruitment and retention
- Non-monetary compensation
- Medical staff incidental benefits
- Professional courtesy
- Health information technology support
- Value-Based Arrangements
- Full Financial Risk value-based arrangements
- Meaningful downside risk value-based arrangements
- Cybersecurity
- Limited remuneration

STARK EXCEPTIONS - OWNERSHIP

- Physician supervision
- Group practices
- In-office ancillary services
- Rural providers
- Whole hospital
- Publicly traded securities
- Intra-family rural referrals

- *Some changes to these provisions, not covered today

STARK PENALTIES

- Stark is fundamentally a payment statute: services provided through improper referral cannot receive payment
- Payments that violate Stark are considered overpayments and must be returned within 60 days
- Civil fines/penalties
  - $26,000+ *per claim*
  - Circumvention scheme $170,000+
  - Can quickly become millions
- Exclusion from participation in federal health care programs
- Can create liability under Anti-Kickback Statute
- Can create liability under the False Claims Act (criminal and civil liability)
  - Repayment, 3x Damages
  - Subject to qui tam claims

CHANGES TO GROUP PRACTICE EXCEPTION

- Changes to 42 C.F.R. 411.352(i)

  – Profits from component of group practice (e.g., an office, subsidiary, or other division) can be shared where there are at least 5 physicians; otherwise, whole-group profits must be distributed(and not further subdivided) between 2 to 5 physicians.

  – Profits must be divided in "reasonable and verifiable manner," including *per capita* distribution, distribution based on non-DHS revenue, or where DHS is less than 5% of revenue and total compensation paid to physician member.

CHANGES TO GROUP PRACTICE EXCEPTION

- Changes to 42 C.F.R. 411.352(i)
  - Clarity for productivity bonuses under 42 C.F.R. 411.352(i)(2).
  - Physician productivity bonuses can be paid based on personally performed services, or services performed "incident to" physician's personally performed services, which is not directly related to the volume or value of physician referrals.
  - Note: volume or value of referrals *can* be reflected if the referred services are billed incident to the physician's personally performed services.

CHANGES TO GROUP PRACTICE EXCEPTION

- Changes to 42 C.F.R. 411.352(i)
  - Examples of productivity bonus examples that are "deemed not to relate directly to the volume or value of referrals" (42 C.F.R. 411.352(i)(2)(ii)(A)-(C)):
    - Bonus based on physician's personally performed RVUs.
    - Bonus is based on services (1) other than DHS, and (2) which would not be DHS if they were payable by Medicare (e.g., not hospital, imaging, PT, DME).
    - The group's revenues from DHS are less than 5% of group's total revenues, and the portion of DHS revenues distributed to each physician is 5% or less of physician's total compensation
  - Documentation required to verify compliance. 42 C.F.R. 411.352(i)(4). Profits derived from VBE participation can be distributed independent of these group and bonus compensation restrictions.

ANTI-KICKBACK STATUTE: GENERALLY

- AKS is an intent-based, criminal statute that prohibits any form of remuneration, whether monetary or in-kind, in exchange for referrals or other Federal health care program business by *any person or entity* (not solely a physician or person acting at a physician's direction). 42 U.S.C. 1320a-7b(b)
- Includes offering, payment, solicitation, and receipt
- "One-Purpose Rule": where one purpose of the payment was to influence referrals, payment is prohibited unless safe harbor applies
- Safe harbor regulations describe voluntary practices that, if fully followed, will not violate the AKS.

AKS: SAFE HARBORS

- Bona fide employment
- Personal services contracts (including those with outcome-based payments)
- Leases for space or equipment
- Investments in group practice
- Ambulatory Surgery Center investment
- Sale of Practice
- Recruitment
- Certain investment interests
- Waiver of beneficiary coinsurance and deductible amounts.
- ACO incentive payments
- Patient engagement and support programs
- CMS-sponsored model arrangements
- Transportation programs
- OB malpractice insurance subsidies
- Electronic health record items or services
- Referral services
- Referral arrangements for specialty services
- Warranties
- Discounts
- Care coordination agreements
- Substantial downside financial risk
- Full financial risk
- Cybersecurity

AKS PENALTIES

- Penalties significantly increased by 2018 bipartisan budget act
- Criminal fines: $100,000 per violation (up from $25,000)
- Civil penalties: $104,500+ (adjusted for inflation annually)
- Jail terms up to 10 years in prison (up from 5)
- Creates liability under False Claims Act
- Exclusion from participation in Federal health care programs
- Civil Monetary Penalties Law, 42 U.S.C. 1320a-7a(a): kickbacks can result in penalties per kickback, plus treble (3x) damages based on the kickback value

SAFE HARBOR CHANGES FOR ~~2022~~ 2023

- Change to the discount safe harbor (42 C.F.R. 1001.952(h)(5)) and creation of new safe harbor (42 C.F.R. 1001.952(cc))
- Was scheduled to take effect on January 1, 2022, but on January 30, 2021, a court ruling delayed implementation of this change until January 1, 2023
- On January 1, 2023, this safe harbor will be changed and no longer protect the following:

  a reduction in price or other remuneration in connection with the sale or purchase of a prescription pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D either directly to the plan sponsor under Medicare Part D, or indirectly through a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, unless it is a price reduction that is required by law.

SAFE HARBOR CHANGES FOR 2023

- This change primarily affects payors and payor-adjacent entities (pharmacy benefit managers, Medicaid managed care organizations), as well as drug manufacturers.

- The disappearance of the discount safe harbor will offset by the entirely new, narrower point-of-sale reductions in price safe harbor under 42 C.F.R. 1001.952(cc).

- This new safe harbor was included in the final rule but never took effect, and its implementation was delayed from January 20, 2021 to January 1, 2023.

SAFE HARBOR CHANGES FOR 2023

- Application of 42 C.F.R. 1001.952(cc), effective January 1, 2023:
  - "remuneration" does not include a reduction in price from a drug manufacturer to a plan sponsor under Medicare Part D or a Medicaid MCO for a prescription product that is payable, in whole or in part, by that sponsor as long as certain conditions are met:
    - Manufacturer and sponsor set the reduction in price in advance, and in writing, by the time of the first purchase of the product at the reduced rate.
    - Reduction in price does not involve a rebate unless the full value of the reduction in price is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback (or series of them).
    - Reduction in price must be reflected in the price of the product at the time the pharmacy dispenses it to the beneficiary.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Behavioral Health:

- SB 69 (peer support recovery services): generally intended to improve peer recovery support systems and resources, create a registration/licensure scheme for peer recovery support services, create a substance use disorder prevention coalition, implement youth risk behavior surveys in schools, and require the Division of Health Care Financing and Policy to post information relating to evidence-based substance use education for K-12 students. Took effect on June 4, 2021, and January 1, 2022 for most purposes.

- Creates a licensing requirement for nonclinical support services in recovery from substance abuse disorders and other behavioral health disorders, which is overseen by the State Board of Health.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Behavioral Health:

- SB 70 (omnibus legislation re: mental health crisis hold processes): developed as part of the 2019-2020 interim legislative committee process; generally made five changes:

  - Revisions to Mental Health Crisis Hold Law (NRS Chapter 433A); distinguishes mental health crisis hold from emergency admission process; defines terms such as "voluntary admission," "emergency admission," and "involuntary court ordered admission;" requires Nevada Attorney General to approve all forms for detainment, evaluation, treatment and conditional release of any person under NRS 433A
  - Assisted Outpatient Treatment (AOT): enacted specific AOT criteria and program procedures and distinguishes AOT process from involuntary court ordered inpatient admission; enables community providers to provide AOT services in coordination with judiciary
  - Conditional Release: enhances coordination and support for transition from inpatient psychiatric services for high-risk individuals
  - Youth Mental Health Crisis Hold: clarify provisions governing hospital-parent interactions when a minor is on a mental crisis hold
  - Chemical Restraint: exclude modern FDA-approved interventions for treatment from the definition of "chemical restraint;" aligns Nevada with federal guidelines.
  - Took effect June 4, 2021, and October 1, 2021, for most purposes

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

- Pharmacy & Prescription Drugs:
  - SB 380 (revises provisions relating to reporting data on prescription drug prices): removes the 2019 requirement that DHHS compile a list of essential asthma drugs; requires DHHS to compile a list of prescription drugs with a wholesale acquisition cost exceeding $40 for a course of therapy; includes pharmaceutical wholesalers as a required reporting entity and expands the information that pharmacy benefit managers (PBMs) must report; took effect October 1, 2021.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Pharmacy & Prescription Drugs:

- AB 177 (Pharmacy Information for Non-English Speaking Patients): generally requires pharmacies to provide prescription and labeling information in languages other than English, upon request of a prescribing practitioner, patient, or other authorized representative. The bill also requires pharmacies to post a notice informing patients that they may request this information, and to include a list of languages in which such information is available, which the State Board of Pharmacy is responsible for approving. A.B. 177 became law on May 28th and took effect July 1, 2021.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Pharmacy & Prescription Drugs:

- AB 178 (Dispensing prescription drugs during declared disasters) – Generally allows a pharmacist to fill a prescription for longer than a 30-day supply for patients residing in an area subject to a declaration of a state of emergency. Took effect July 1, 2021.

- Note that Nevada's COVID-19 state of emergency remains in effect. Despite rescission of mask mandate, the authority to renew the mandate and exercise other powers remains in effect.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Pharmacy & Prescription Drugs:

- SB 396 (Public Agency Contracts for Prescription Drugs): requested by the Interim Committee to Study the Costs of Prescription Drug, S.B. 396 generally authorizes state agencies to enter into contracts with private entities outside Nevada for the purpose of purchasing prescription drugs, pharmaceutical services, or medical supplies and related services.

- Authorizes DHHS to enter into an agreement for the purchase of prescription drugs for Medicaid or the Children's Health Insurance Program. The Governor signed S.B. 396 into law on June 2nd, 2021 and it took effect on passage and approval.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Other Healthcare Bills

- SB 40: requires, to the extent that federal money is available, DHHS to establish an all-payer claims database (APCD) of information relating to health insurance claims resulting from medical, dental, or pharmacy benefits provided in Nevada.

- Requires DHHS to establish an advisory committee to assist in establishing and maintaining the database and requires DHHS to adopt regulations pertaining to APCD establishment and maintenance. Any public or private insurer that provides health benefits and is regulated under state law is required t submit data to the APCD. The legislation was purportedly intended to promote transparency measures and help monitor and analyze trends within the healthcare sector. Took effect on July 1, 2021, and Jan. 1, 2022 for most purposes.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Other Healthcare Bills

- AB 47 (State-Level Hart-Scott-Rodino Reporting): enacts State-level reporting requirements that mirror the federal Hart-Scott-Rodino (HSR) Antitrust Improvement Act of 1976. The bill requires health care practice groups who are already subject to HSR antitrust reporting requirements to additionally report information relating to mergers or acquisitions and other transactions to the Nevada Attorney General.

- HSR reporting thresholds are set by the FTC and adjusted for inflation. For 2022 these thresholds are transactions of over $101 million, or transactions where one party has sales or assets of at least $202 million and the other party has sales or assets of at least $20.2 million; all transactions valued at more than $403.9 million generally require pre-merger notification. These thresholds are more than 9.75% greater than the 2021 thresholds.

- A.B. 47 also relaxes restrictions on non-compete agreements under NRS 613.195 and prohibits an employer from bringing an action to enforce a non-compete agreement in certain circumstances. Despite significant opposition to this bill throughout the legislative session, the Governor signed A.B. 47 into law on May 26th. The bill took effect on October 1, 2021.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Other Healthcare Bills

- AB 278 (Expanding NV Board of Medical Examiners' authority over practitioners): expanded authority of Nevada Board of Medical Examiners to request information and data pertaining to a medical practitioner's practice as a part of the licensure renewal process. Took effect October 1, 2021 for most purposes.

- SB 184 (Physician Assistant Licensure): relaxes physician assistant licensure provisions and other regulatory requirements. The bill prohibits the Board of Medical Examiners and the State Board of Osteopathic Medicine from requiring physician assistants to obtain certification from the National Commission on Certification of Physician Assistants for purposes of satisfying continuing education requirements and establishes provisions allowing physician assistants to obtain licensure from multiple boards for reduced fees. The bill was signed into law on May 27th and took effect, for purposes of adopting regulations, on passage and approval. Several other provisions of the bill became effective on January 1, 2022.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Other Healthcare Bills

- AB 436: amends NRS 686A to mandate that an insurer shall not contract with the provider of vision care services for any rate of reimbursement if the insurer has an ownership or other pecuniary interest in the rate of reimbursement. the bill prevents insurance companies from having any interest in vision care services directly.

- Comparison: This attempts to preempt a situation analogous to an insurer from obtaining an HMO license from the Division of Insurance and allowing the insurer to act as a payor as well as a provider. The bill's purpose is to create a wall between vision insurance and providers of vision services.

- They can only negotiate contracts and provide reimbursement for services but cannot have any ownership interest or monetary interest in the vision services themselves. Took effect Jan. 1, 2022.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Other Healthcare Bills

- SB 305: prohibits providers from using discriminatory practices when making decisions regarding organ transplants based on a person's disability. Although arguably intended to promote equity in organ transplant decision-making, the law may put providers in an untenable position of determining who the most "worthy" recipient of an organ transplant would be based on factors a provider may not be in the best position to evaluate. Effective October 1, 2021.

- Due to limited scope of transplant activity in Nevada presently, this may be of relatively small scope. If the range of organ donations within Nevada increases, however, this may create an issue for providers and donation coordinators.

- This law also interacts with Section 1557 of the Affordable Care Act, which prohibits discrimination in providing federally-funded healthcare. Section 1557 was the basis for legal action in early 2020 when certain states enacted emergency plans that called for rationing of care or resources based on likelihood of survival and other criteria that implicated protected categories such as age and gender.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Other Healthcare Bills

- SB 329 (Healthcare Groups mergers and acquisition reporting): similar to A.B. 47, S.B. 329 requires hospitals and physician practice groups to notify the Department of Health and Human Services of any merger, acquisition, or similar transaction in which they are involved if the physician group satisfies certain criteria based on its size in the market.

- Requires practice groups that represent at least 20% of physicians in a specialty within a primary service area, and the physician group represents the largest number of physicians of any physician group practice that is a party to (or owned by a party to) the transaction to report any merger or acquisition to the Department of Health and Human Services and requires the Department to post the information publicly and publish a report based on the information.

- S.B. 329 prohibits health care providers and facilities from entering into, offering to enter into, or soliciting a contract that prohibits a third-party insurer from steering covered persons to certain care providers, or placing providers in tiers. S.B. 329 generated a fair amount of controversy, but the Governor signed the bill into law on June 8, 2021. For administrative rulemaking purposes, the bill became effectively immediately. Otherwise, the bill took effect on October 1, 2021.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

The "Public Option" in Nevada

- SB 420 (Nevada Public Health Insurance Option Legislation): requires the Director of the Department of Health and Human Services to design, establish, and operate a public health benefit plan, commonly referred to as the "Nevada Public Option," in consultation with the Silver State Health Insurance Exchange and the Nevada Insurance Commissioner.

- Insurers that bid to provide coverage to Medicaid recipients will be required to offer the Public Option, which must be available to all natural persons who reside in Nevada, through the health exchange and through direct purchase. The Public Option may be made available to small businesses and employees. S.B. 420 passed on party lines and became law on June 9, 2021. The bill took effect immediately for purposes of procurement and preparing administrative tasks necessary to carry out the bill. Most substantive provisions become effective January 1, 2026.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Implementing Regulations – 2022-2023 Interim

- LCB File R056-20 – NV State Board of Health (filed Jan. 4, 2022): adds new definitions to NAC 449 for "Alzheimer's disease" as a "form of dementia caused by irreversible, progressive brain disorder that slowly destroys memory, thinking, and the ability to carry out tasks of daily living," and "dementia" as "loss of cognitive functioning and behavioral abilities [including] memory, language skills, visual perceptions, problem solving," and others; proposes other changes that would prohibit a residential facility that cares for persons with Alzheimer's disease or other forms of dementia from admitting and retaining a patient who requires "containment in locked quarters;" proposed related changes to **NAC 449**.
- LCB File R085-20 – NV State Pharmacy Board (filed April 14, 2021): establishes fees for the investigation or issuance of an original license and biennial review of a license to conduct a pharmacy in a recovery center or an ambulatory and surgical center; proposed related changes to **NAC 639**.
- LCB File R179-20 – NV Chiropractors Board (filed Dec. 22, 2021): outlining and prescribing requirements for the issuance of a license by endorsement for chiropractors who hold a corresponding valid and unrestricted license in another jurisdiction; proposed related changes to **NAC 634**.

NEVADA LEGISLATIVE UPDATE: 81ST (2021) SESSION

Implementing Regulations – 2022-2023 Interim

- LCB File R003-21 – NV Pharmacy Board (filed Dec. 22, 2021): reduces the fee for the authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances, and for the biennial renewal of such authorization from $200, to $80; proposed related changes to **NAC 639.**
- LCB File R013-21 – NV Pharmacy Board (filed Oct. 28, 2021): adds fees for the licensing of automated drug dispensing systems and for the certification of mechanical devices, and requires an automated drug dispensing system to track who uses the system, what drugs are in the system, the system's temperature, and related information to ensure that the drugs are safely stored and only dispensed to an authorized person; proposed related changes to **NAC 639**.
- LCB File R025-21 – NV Pharmacy Board (filed Sep. 30, 2021): provides that an application for any certificate, license, or permit issued by the Pharmacy Board is only valid for 1 year after the application is received; increases fees from $500 to $1,000 for the investigation, issuance, or renewal of a license as a drug manufacturer or wholesaler (per SB 408 (2021)); proposed related changes to **NAC 638 & NAC 639**
- LCB File R035-21 – NV Board of Dental Examiners (filed Nov. 4, 2021): requires Dental Board to issue to a licensed dentist, dental hygienist or dental therapist, a special endorsement to administer immunizations for influenza only if the licensee completes a related course of training that the Board approves; proposed related changes to **NAC 631**.

QUESTIONS?

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