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Risk Management and Patient Safety News

# Ketamine – What's All the Hype About?

by Monica Ludwick, Pharm.D

In the new year alone, ketamine has already made headlines in dozens of articles highlighting its increased off-label use. There has been a significant increase in exposure and interest for this old drug that seemingly has new tricks up its sleeve.

Ketamine received FDA approval in the early 1970s, only for use in induction and maintenance of anesthesia. Unlike other anesthetics, ketamine essentially "disconnects" the brain from the body's sensations. Its hallucinogenic effects stem from the expanded awareness that results when the brain loses its ability to process incoming information from the body.[1-3]

Although ketamine, a schedule III controlled substance, has many off-label uses, the FDA currently does not offer any guidance for its use via alternative routes of administration and indications. In general, once a medication is FDA approved, healthcare providers may prescribe the drug off label for unapproved uses, often because of a patient's condition and failing conventional therapy, or because no current medication is approved for his or her rare medical condition.[1]

Ketamine's effectiveness led to the FDA approval in 2019 of Spravato, the S-enantiomer of ketamine, for treatment of treatment-resistant depression (TRD) and major depressive disorder (MDD), via an inhaled device. However, the recognition of its potential adverse effects has led to significant restriction for use via the FDA Risk Evaluation and Mitigation Strategies (REMS) program.[4]

While off-label IV ketamine may be beneficial to some patients with mood disorders, it is important to consider the limitations of the available data and the potential risks associated with the drug when considering its use as a therapeutic option.

## Concerns with Ketamine Therapy

Although the exact mechanism of action is unknown, ketamine's antidepressant activity has made it appealing to many patients seeking relief. Currently, there are no long-term studies about the effects of ketamine as opposed to many other conventional antidepressants. Also, ketamine is not 100 percent effective, like many other antidepressant treatments in existence. It is imperative to screen patients seeking ketamine thoroughly and monitor patients throughout ketamine therapy. Ketamine's psychoactive properties can cause fatigue, restlessness, anxiety, dizziness, and hallucinations — all which makes its off-label use tricky to manage clinically. Ketamine can increase heart rate and blood pressure. There are also some concerns over risks to the liver, bladder, and kidneys.

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Another concerning issue is the increasing ability of ketamine to serve as a gateway drug to other psychedelics. A growing practice, known as "microdosing," involves taking minute quantities of drugs such as LSD, psilocybin, or mescaline every few days. The trend of patients who are undergoing both ketamine treatments and microdosing with other psychedelics is worrisome.[5] A prior claims data search found a case where a patient turned to LSD believing ketamine was no longer effective. Once the clinician discovered the concurrent LSD use, the ketamine was discontinued despite the patient's multiple pleas. The patient subsequently stopped seeing the clinician.

## Considering Offering Ketamine Therapy?

The global behavioral health market is forecasted to reach around $240 billion by 2026, currently sitting at about half that amount.[6] This should come as no surprise as depression is the leading cause of disability worldwide, and its incidence has only increased as the pandemic continues.[7]

With single ketamine treatments costing anywhere from four hundred to several thousand dollars, providing ketamine therapy can be lucrative. Although many patients are reporting relief with treatment, some physicians worry that unscrupulous practices by ketamine providers may be taking advantage of a susceptible population with the appeal of a quick fix and hefty price tag.

The FDA's approval of Spravato may have kickstarted psychedelic-assisted therapy options as several clinical trials have been fast-tracked by the FDA since then. Perhaps the lack of regulatory oversight on ketamine clinics may change as more psychedelics gain FDA approval. Because there is no regulation for the control and oversight of off-label ketamine, it's a free-for-all on how the business is operated – including whether patient safety protocols are implemented. In contrast, Spravato has strict administration requirements and restrictions that ketamine clinics may be circumventing.

After all things considered, clinicians who are looking into providing ketamine therapy should have the following safety considerations in mind:

- Careful selection of patients for treatment via thorough medical and psychiatric evaluation, including history of drug dependence and potential for abuse.
- Providers should follow a guideline or protocol, ensuring all safety parameters are followed. Home treatment would not facilitate accurate safe monitoring. Unlike naloxone with opioids, there are no medications available to reverse the effects of ketamine that could rescue a patient, if needed.
- Patient monitoring should be done in collaboration between administrating provider and the mental health provider. Most patients seeking ketamine therapy are challenging patients, who are resistant to standard treatments, and often require continuous treatment.
- Caution should be taken when marketing the drug's benefits on websites or other educational material where the clinical evidence is questionable.
- **Although ketamine infusions can be administered by any licensed physician, those who are trained in its use have a high level of expertise and experience, which are indispensable qualities in assuring the safest and most successful outcome for their patients.**

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[6]Behavioral Health Market (By Disorder: Alcohol Use Disorders, Schizophrenia, Bipolar Disorder, Depression, Anxiety, Post-Traumatic Stress Disorder, Substance Abuse Disorders, Eating Disorders, Others; By Service: Emergency Mental Health Services, Outpatient Counseling, Home-Based Treatment Services, Inpatient Hospital Treatment Services, Others) - Global Industry Analysis, Market Size, Opportunities and Forecast, 2019 – 2026. Behavioral Health Market Size Worth US$ 240 Billion by 2026 (acumenresearchandconsulting.com)

[7]Ettman et al. Persistent depressive symptoms during COVID-19: a national, population-representative, longitudinal study of U.S. adults. The Lancet Regional Health - Americas, Volume 5,2022, doi: 10.1016/j.lana.2021.100091.

# Direct Democracy in California – The Ballot Initiative Process

by Gabriela Villanueva

Initiatives are state or local legislative measures placed on the ballot by a group of citizens by means of a petition signed by a specified percentage of voters and enacted by a majority of the voters. The initiative process has been called California's fourth branch of government, a frank recognition of the expanding role it plays in setting the state's policy agenda.

Historically, the initiative process in California first arose out of the advocacy efforts of a then newly-formed Progressive political party with the support of the labor movement. It was a means to circumvent a state government in which the Southern Pacific Railroad and special interests were perceived as having too much power. By 1907, Los Angeles, Pasadena, San Diego, San Bernardino, Fresno, Sacramento, and Vallejo had all adopted city initiative and referendum ordinances. In 1911, voters followed the lead of Progressive Governor Hiram Johnson, and California became the tenth state to enact the initiative, referendum, and recall processes.

Over the last 100 years, California has become one the heaviest users of the initiative process. With a state as large, populous, and geographically diverse as California, it is not a surprising occurrence.

Case in point: the upcoming midterm general election taking place this November.

At last count, the Secretary of State's website lists nearly 50 ballot initiatives moving through the qualifying process. Of that total, 33 are cleared for circulation, eight are pending with the Attorney General's office, three have become fully eligible for the November general election, one is qualified for the ballot, and five others have been withdrawn or failed to qualify. Another eight to 12 additional initiatives will likely become fully eligible to appear on the November ballot.

Of the three initiatives that are already fully eligible, there is one of specific interest and concern to CAP and all California physicians. The initiative is entitled, "Adjust Limitations in Medical Negligence." It is an initiative spearheaded by an out-of-state plaintiffs' attorney and aims to drastically weaken the protections afforded to physicians by the Medical Injury Compensation Reform Act, better known as MICRA. This initiative will once again see CAP engaged in an all-out effort to secure those protections imparted to physicians by this long-standing law. And California voters will once again play a deciding role in this practice of direct democracy when they vote on this initiative in November.

**Eligible Statewide Initiative Measures:**
https://www.sos.ca.gov/elections/ballot-measures/initiative-and-referendum-status/eligible-statewide-initiative-measures

*Gabriela Villanueva is CAP's Government and External Affairs Analyst. Questions or comments related to this article should be directed to GVillanueva@CAPphysicians.com.*

Public Policy

Ask My Practice

by Andie Tena

# At-a-Glance: 2022 Billing and Coding Updates for Medical Practices

In today's ever-changing healthcare environment, it's important to have resources to keep you up to date on issues affecting patient care and practice revenue. CAP is here to support all members with vital updates.

In January, CAP hosted a webinar with healthcare business operations and reimbursement management expert, Mary Jean Sage, addressing critical 2022 billing and coding updates.

The webinar covered changes impacting ICD10-CM, CPT, HCPCS, Medicare payment provisions, telehealth, and MIPS.

Did you know, there are 159 additions, 32 deletions, and 20 revisions in the ICD 10 coding book in 2022 and 405 editorial changes that incorporate a series of 15 vaccine-specific codes to efficiently report and track COVID-19 immunization and administrative services?

**That's why the importance of consistent, complete documentation in the medical record cannot be overemphasized. Without such documentation accurate coding cannot be achieved**.

Here is a summary of a few key changes that medical practices should implement as soon as possible:

### Care Management Updates

- There are separate codes depending on who performed the service – physician or other qualified health professional (QHP) or clinical staff
- Accurately document time (first 30 minutes vs. additional 30 minutes)

### HCPCS Level II Changes (Purchase a New Book Annually)

- 155 New Codes
- 63 Revised Codes
- 48 Deleted Codes
- New Modifiers

### Senate and House Bill - December 2021

- Delays 2% cuts to Medicare through March 2022
- Delay's sequestration 4% cuts to 2023
- 3.75% reduction in MPFS changed to a 0.75% reduction



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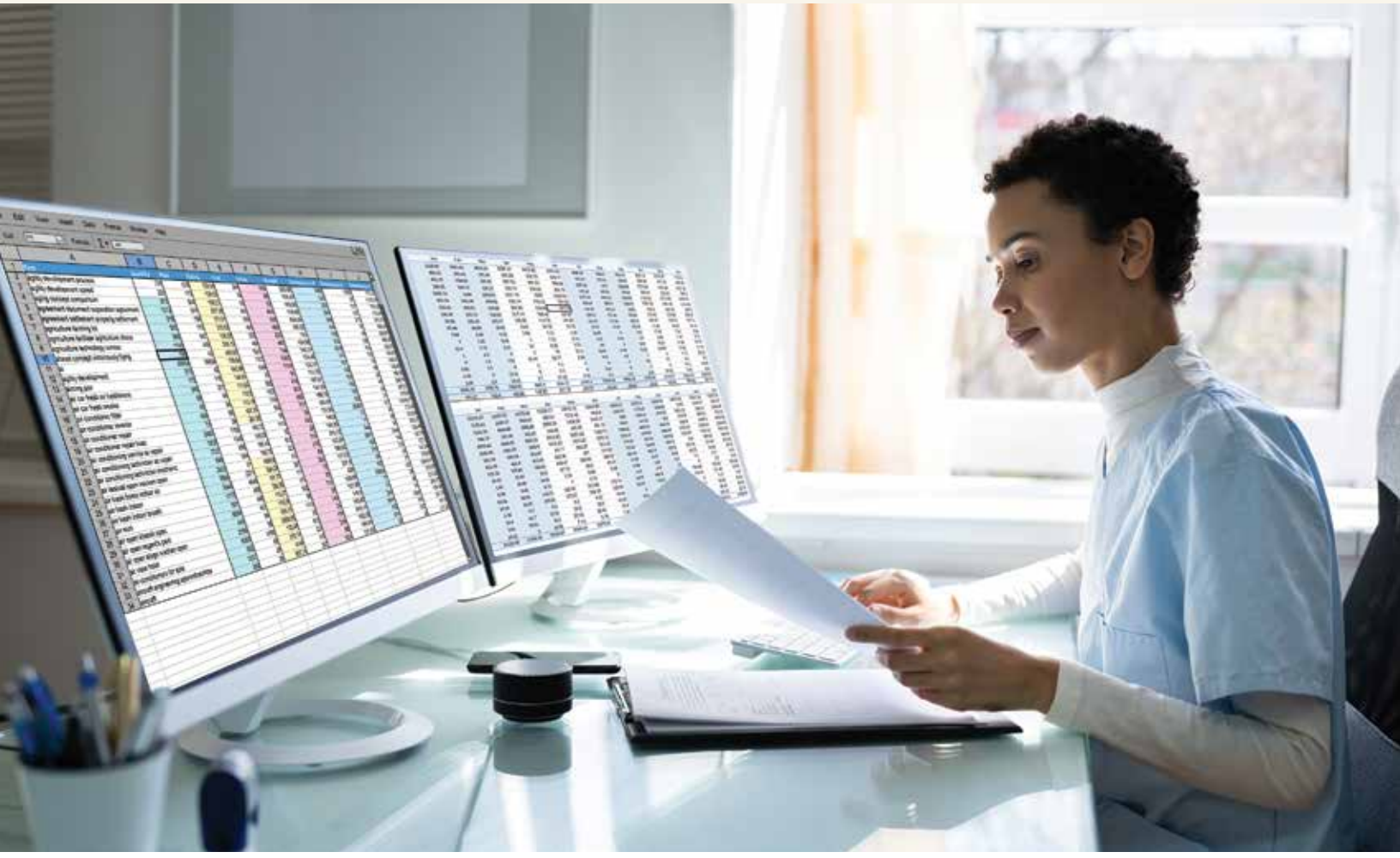
In 2021, the AMA added the concept of shared services between a physician and qualified healthcare professional (QHP)

- CMS uses the term non-physician practitioner (NPP)
- Both QHP and NPP mean someone who has E/M in their scope of practice
- Allows for E/M services to be jointly performed by a physician and NPP

For a comprehensive overview of all critical 2022 billing and coding changes, please view the webinar, "Critical 2022 Billing and Coding Updates for Your Medical Practice," now available for free on demand at **www.CAPphysicians.com/billingandcoding**.

As a benefit of your membership, take advantage of CAP's *My Practice* program for free practice management and business assistance. In addition to being available for general practice-related inquiries, *My Practice* can provide you with support for billing and coding inquiries and connect you with essential resources.

*Andie Tena is CAP's Director of Practice Management Services. Questions or comments related to this column should be directed to ATena@CAPphysicians.com.*



# Cal/OSHA Empowered by California Senate Bill 606

### Here are some things employers need to know:

California's new Senate Bill 606 went into effect January 1, 2022, and includes two components that put more punch in Cal/OSHA's power to enforce workplace regulations and penalize violations. Cal/OSHA's expanded ability to pursue enterprise-wide citations by presuming multiple site violations when inspecting, and ability to issue citations for egregious violations has been bolstered by this bill.

### Enterprise-Wide Violations

SB 606 now allows Cal/OSHA to take into consideration the employer's history at all locations and possibly use that history to invoke an enterprise-wide violation with or without inspection at each site. The bill also authorizes Cal/OSHA to issue an enterprise-wide citation requiring abatement if the employer fails to rebut such a presumption. Abatement may potentially require an employer to cease practice or close until a statement of abatement, certifying that the employer has acted and shown specifically what has done to fix each violation, is filed and accepted by Cal/OSHA. Managers who interact with Cal/OSHA need to pay close attention to their communications during an inspection and provide pertinent information to reduce the risk of enterprise-wide violations. Handling any Cal/OSHA citation at all sites with careful attention to avoid the "pattern and practice" trigger, which under SB 606 allows Cal/OSHA to invoke enterprise-wide citations, should be considered.

### Egregious Violations

If Cal/OSHA determines an employer has egregiously and willfully violated an occupational health regulation, SB 606 authorizes them to issue a citation for an "egregious violation" order, or regulation. A violation is considered "egregious" if one or more of the following is true:

- The employer intentionally, consciously, with voluntary action or inaction, made no reasonable effort to eliminate the known violation.
- The violations resulted in worker fatalities, a worksite catastrophe, or many injuries or illnesses.
- The violations resulted in persistently high rates of worker injuries or illnesses.

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- The employer has an extensive history of prior violations.
- The employer has intentionally disregarded its health and safety responsibilities.
- The employer's conduct, taken as a whole, amounts to clear bad faith in the performance of its duties.
- The employer has committed many violations that has significantly undermined the effectiveness of any safety and health program that may be in place.

Each instance of an employee's exposure to an egregious violation is a separate violation. This could result in extremely large penalties imposed by Cal/OSHA. Also, once a violation is determined to be egregious, the determination is in effect for five years.

## Here are some things for employers to consider:

- Regularly review Cal/OSHA regulations to ensure that your workplace is in compliance.
- Maintain a strong safety culture in the workplace.
- Foster effective communication, employee training, and comply and cooperate with all auditing and inspection requests by Cal/OSHA.
- Employers should review their written policies to ensure compliance with Cal/OSHA standards.

The Cooperative of American Physicians would like members to be aware of the increased power Cal/OSHA now wields because of SB 606. Even if you have a small practice without multiple locations, you could still be at risk of enhanced penalties and enforcement mechanisms provided to Cal/OSHA under this new law. CAP physician members are reminded to continually evaluate and update their workplace safety protocols and policies to protect their patients, employees, and practices.

For more information and for questions about business insurance coverage for your practice, please contact CAP Agency at 800-819-0061 or at CAPAgency@CAPphysicians.com.

**Resources:**

Full Text of California Senate Bill 606: Bill Text - SB-606 Workplace safety: violations of statutes: enterprise-wide violations: egregious violations. (https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB606)

Cal/OSHA Website: Cal/OSHA - Division of Occupational Safety and Health - Home Page (www.dir.ca.gov/dosh/)

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# Case of the Month

This month, we feature an article from the archives written by CAP's former General Counsel Gordon Ownby

## Put the Patient in the Information Loop

An abnormal test result typically sets in motion a number of follow-up actions by a patient's treaters. While many of those actions will depend on the particular situation, one of them should be a constant: Telling the patient.

A 51-year-old woman visited Dr. GS, a general surgeon, on a referral after an abnormal mammogram. The patient reported that her mother had a lumpectomy for breast cancer at age 65 and other family members experienced leukemia and bone, colon, and lung cancer. Dr. GS viewed the recent screening and diagnostic mammograms and noted marked density in both breasts with a particular 3 cm density on the lower right breast. An in-office ultrasound revealed a large dilated duct in the same area as the 3 cm density as well as multiple images consistent with cystic lesions. Dr. GS ordered an MRI and a colonoscopy and provided the patient with education and a care plan.

The patient returned three days later with a fever and right breast pain with streaking and redness. Dr. GS noted a swollen right breast with blotchy erythema and a hardened quadrant from 6-9 o'clock. Dr. GS' working diagnosis was mastitis. Dr. GS started the patient on Keflex and dicloxacillin. The patient returned three days later, feeling better. Another ultrasound showed increased fluid collection. Dr. GS recommended the patient return in three to four days, at which time they would consider the previously recommended MRI.

When the patient returned two weeks later, Dr. GS' nurse practitioner noted quadrants of mass-like hardening of the right breast and instructed the patient to now have her MRI, as the mastitis had improved.

The radiologist noted the MRI showed "multiple concerning lobulated enhancing masses localized in the lower inner quadrant...suspicious...directed ultrasound of area is needed. Ultrasound guided biopsy will be needed if lesions are identifiable. If not, MRI-guided biopsy will be recommended." The radiology office sent the report to Dr. GS, but only told the patient of the need for follow-up studies.

Several days later, Dr. GS' physician assistant sent an internal office memo to the front office staff asking if the patient had yet had the recommended biopsy. The front office told the PA that according to the radiology facility's portal, the patient had an appointment for an ultrasound coming up. On the day after that scheduled (but failed) appointment, Dr. GS' physician assistant initialed the original MRI report as read. No follow-up was scheduled. The radiology facility did not advise Dr. GS' office of the failed appointment.

Approximately 30 months later, the patient had a new screening mammogram that revealed a new mass. An MRI and biopsy confirmed a malignancy in the right breast. The patient returned to Dr. GS, who noted a large palpable mass on the right breast but no enlargement in the nearby lymph nodes. Dr. GS recommended a mastectomy and ordered a PET scan to rule out metastasis. After the scan came back as negative, Dr. GS discussed several treatment options and ultimately scheduled the patient for a bilateral mastectomy. Dissection during the procedure found three positive lymph nodes out of 34.

Postoperatively, the patient complained of arm numbness, lymphedema, and decreased mobility in her



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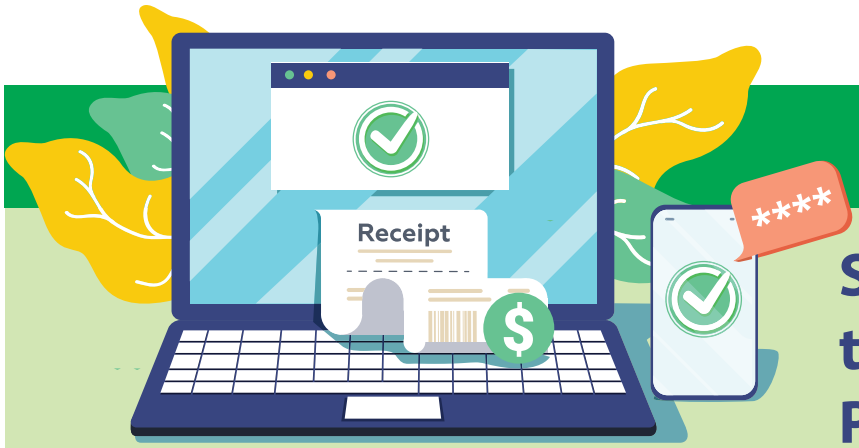
arm. She had to stop chemotherapy because of severe side effects, but was able to undergo external beam radiation therapy. The patient's suit against Dr. GS for medical negligence was resolved informally prior to a trial.

Dr. GS' office's attempt to track the patient's pursuit of the recommended biopsy was likely handicapped by the patient's ignorance of the matter's urgency. The best "tickler" trails will be those that include telling a patient of an abnormal finding and explaining why further care is needed.




# Sign Up to Enjoy the Benefits of Paperless Billing

CAP understands that saving time is more critical now than ever. That is why you shouldn't wait any longer to sign up for paperless billing and enjoy the ease and convenience of managing your CAP account online.

Enrolling in paperless billing lets you receive your CAP statement via email, pay your bill online, and manage your account easily through a secure portal.

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1. Visit **https://member.CAPphysicians.com** to log into your CAP account. If you do not have an account, you will need to visit **https://member.CAPphysicians.com/register** to create one.
2. Once logged in, select the green "Set Up Paperless Billing" button to the left of the screen.
3. Select the "Via Email Only" button.
4. Verify your email address and click the "Save Changes" button.

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*We welcome your comments! Please submit to communications@CAPphysicians.com.*

# Your Practice Staff Can Earn $100 by Completing CAP's New Risk Management Institute

The Cooperative of American Physicians is pleased to offer its newly revised and updated Risk Management Institute exclusively to CAP member practices at no cost. This essential online course is designed specifically for office staff and offers actionable lessons for reducing risk and strengthening patient safety protocols.

**CAP's new and improved Risk Management Institute provides six 20-minute training modules covering:**

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- Tracking and Recall
- Medical Record Management

## Enrolling is Easy and Free!

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## How to Earn the $100 Incentive

Staff members who enroll in the Risk Management Institute are eligible to earn a $100 gift certificate upon completion of all six training modules within a six-month timeframe (limit of one $100 gift certificate per staff member). Additionally, the practice must complete a Virtual Practice Visit; a Virtual Practice Visit within the last 36 months is also acceptable.

The Virtual Practice Visit is another no-cost benefit of your CAP membership. During the Virtual Practice Visit, a CAP Risk Management and Patient Safety Specialist will help you evaluate your existing office protocols, recommend operational enhancements, and avoid common scenarios that can put you at risk of a medical malpractice lawsuit.

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