Compliance Check-In:
Current Issues in Health Care Compliance

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Goal and Groupings for Today's Presentation

Goal

- Identify key compliance risks for health care providers, helping their compliance professionals, executives, and legal counsel prepare for 2022.

Groupings

- Risks arising directly from Covid
- Risks that developed alongside Covid

Key Compliance Risks

Risks Arising from Covid

- Data Reporting; Returning Unused Funds
- Covid Uninsured Program
- Telehealth Changes
- Waivers

Risks that Developed Alongside Covid

- Billing & Coding Changes
- 2021 Stark and AKS Rules: Planning for 2022 Compliance Work Plan
- Opioid Prescribing and Treatment
- Pre-Covid Risk Assessments & Work Plans

Risks Arising from Covid

Provider Relief Fund; Reporting and Return

- Health care providers have received billions of dollars in relief fund payments from the Provider Relief Fund ("Relief Fund") created by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act")
- For reporting, providers who received more than $10,000 in Relief Fund payments must report COVID expenses and lost revenue through an HHS online portal
  - Reports generally describe how funds were used
  - First Due Date: September 30, 2021 (for funds received prior to June 30, 2020)
  - 60-day grace period announced for this round of reporting
  - Second Due Date: March 31, 2022 (for funds received in July-December, 2020)
- **Compliance risk**: Recoupment or other enforcement actions

Compliance Takeaways – Provider Relief Fund Reporting

Policies & Procedures

- Ensure Provider Relief Fund compliance issues are on your 2022 Work Plan.
- Consider addressing organization's approach to unused funds in Work Plan or policy.
- If your organization is covered by the Single Audit requirement, review the existing process and update as necessary.

Compliance Officer & Compliance Committee

- Coordinate compliance activities related to Relief Fund with Reimbursement and Finance.
- Monitor OIG's Relief Fund reports and any published corrective actions to calibrate your organization's Relief Fund compliance activities.

Training & Education

- Educate impacted employees regrading any policy updates.

Auditing & Monitoring

- Monitor the ways in which Relief Fund money is used.
- Meet reporting and Single Audit deadlines.
- Ensure any unused funds are returned to government (Return Unused PRF Funds Portal and Pay.gov)

Covid Uninsured Program

- Also called HRSA Claims Reimbursement Program
- HRSA-administered program to reimburse for Covid testing, treatment, and vaccination for the uninsured
- Only able to be used for costs/losses not otherwise reimbursed; provider must return funds to government if payment received from elsewhere
- No opportunity for interim bills or corrected claims; all claims are full and complete, and all payments are final
  - Refund process available for overpayments
- **Compliance risk**: Potential overpayments and False Claims Act liability

Compliance Takeaways – Covid Uninsured Program

Policies & Procedures

- Ensure Covid Uninsured Program compliance issues are on your 2022 Work Plan
- Establish policies for handling patient payments for care that is reimbursed under the Covid Uninsured Program

Training & Education

- Ensure billing department employees are appropriately trained on procedures for submitting claims to Covid Uninsured Program

Auditing & Monitoring

- Include Covid Uninsured Program claims within claims reviews

Identifying Noncompliance & Corrective Action

- Investigate suspected overpayments
- Refund overpayments consistent with current HRSA guidance

Telehealth Changes

- Telehealth expanded rapidly due to waivers
- Some changes will be permanent, driven by regulatory updates
- **Compliance risk**: OIG has included several audits focusing on telehealth on its Work Plan
  - Consistent focus: Whether services provided remotely meet Medicare billing requirements

Telemedicine Basics Defined

Before COVID-19 PHE Waivers

- **Originating Site** – Medical facility where patient is located. This facility bills Q3014 for a flat fee reimbursement for its role facilitating the patient visit.

- **Distant Site** – Medical facility where provider is located during the telehealth visit. For Medicare and Medicaid, billed with Place of Service code 02 for telemedicine and no corresponding modifier. Commercial payors required the use of modifier 95 to indicate a telemedicine service.

Telemedicine Basics Updated During the PHE Waivers

Before COVID-19 PHE Waivers

- Updates – Both of these location definitions have been relaxed during the PHE.
- The provider is now permitted to provide telehealth approved services from their homes.
- Patients are encouraged to receive telemedicine services from their own homes.

Originating Site

- Patients are not required to be in a rural area. In fact, they can be in any place with a reasonable HIPAA privacy safeguards and working audio-visual, real time, two-way communication.
- Patients are encouraged to present from home during the COVID-19 pandemic and the Q3014 facility fee is not billed.

Telemedicine Basics Updated During the COVID-19 PHE Waivers

Distant Site

- During the PHE, the provider is permitted to provide telehealth approved services from their homes and other locations with reasonable HIPAA privacy safeguards. Such reasonable precautions could include using lowered voices, not using speakerphone, or recommending that the patient move to a reasonable distance from others when discussing PHI.

- CMS instructs providers to bill with the POS that they would have normally used to provide the service. This billing practice allows providers to receive the full reimbursement for the telemedicine service. Be sure to apply modifier 95, as this has been reinstituted to identify telemedicine services.

Telemedicine Basics Updated During the COVID-19 PHE Waivers

Professional Licensure

- Although the "normal POS" is used on the claim for billing purposes, the *actual* place of service is where the patient is located. The physician must be licensed to practice medicine in the state where the patient is located.
- There might be some state license flexibilities during the PHE but confirm that with each state at issue.
- There is also an Interstate Medical Licensure Compact between several states that may provide for a faster licensure approach.

Telemedicine Equipment

- Audio/Visual Equipment
  - Use technology that has two-way real-time, interactive audio and visual capabilities as long as they are not public-facing, e.g., Facebook Messenger video chat, Apple FaceTime, Google Hangouts or Skype are allowed.
  - Technologies such as Facebook Live, TikTok and Twitch are not permitted.

Telemedicine Equipment

Audio Only Telephone Communication

- During the COVID-19 public health emergency, Medicare as well as many private payers have approved coverage of telephone only (no video) services billed using an existing set of CPT codes (99441–99443) for physicians and non-physician practitioners. CMS makes separate payment for healthcare practitioners who cannot independently bill for E/M phone visits, e.g., therapists, social workers, and clinical psychologists using code set 98966-98968.

- These services are not considered telemedicine visits and modifier 95 is not applied.

Telemedicine and Other Equipment and Other Visits

- Telehealth visits refer to visits that would normally be done in person. The following visit types, along with telephone calls, are not telehealth visits:

- Virtual check-ins
  - Professionals bill for brief (5–10 min) communications that mitigate the need for an in-person visit and can be furnished via any synchronous telecommunications technology. During the PHE waivers, both new and established patients can receive these services. The virtual check-in must not be related to any medical visit in the next 24 hours or previous seven days. Bill for this service using code G2012.

- Remote evaluation
  - A professional evaluates a prerecorded video or image the patient sends to the provider. Provided all criteria are met, the service can be billed using code G2010.

Telemedicine and Other Equipment and Other Visits

- E-visits
  - An established patient can generate an initial non-face-to-face encounter via an online patient portal.
  - Providers bill for this online E/M service for time accumulated over seven days using codes 99421–99423.
  - Healthcare professionals that do not qualify for billing E/M services can bill their time in the same way, accumulated over seven days.
    - The qualified nonphysician healthcare professionals include psychologists, speech language pathologists, occupational therapists, and physical therapists.
    - These professionals may use codes G2061–G2063.

2022 – Physician Fee Schedule Proposed Rule

- In the 2022 PFS proposed rule, CMS is proposing to allow certain services added to the Medicare telehealth list to remain on the list to the end of December 31, 2023, so that there is a glide path to evaluate whether the services should be permanently added to the telehealth list following the COVID-19 PHE.

Compliance Takeaways – Telehealth Changes

Policies & Procedures	Training & Education	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
• Create telehealth policy(s)	• Provide education to providers on Telehealth coding and billing requirements and documentation	• Perform Telehealth audits for documentation and billing requirements	• Identify claims with potential overpayments and refund according to CMS/payor guidelines

Covid Waivers

- Federal and state waivers allowed for expediency in responding to Covid
- Waivers will expire with Public Health Emergency declarations (or earlier)
  - Federal PHE extended until January 16, 2022
- Some states have rescinded their Public Health Emergencies
- **Compliance risk**: Pandemic has gone on so long that waivers are now standard operating procedure

Compliance Takeaways – Covid Waivers

Policies & Procedures

- Consider issuing temporary policies and procedures consistent with waivers

Compliance Officer & Compliance Committee

- Continually monitor status of public health emergency declarations (both state and federal)
- Reconcile any impact based on state action
- Identify operational areas that have come to rely on waivers

Training & Education

- Train individuals on any new policies and procedures implemented due to waivers
- Communicate with areas of organization that rely on waivers; encourage planning for post-waiver environment

Auditing & Monitoring

- Ensure claims that rely on waivers include appropriate modifiers
- Monitor areas that rely on waivers as PHE comes to a close
- Consider incorporating Covid waiver compliance into 2022 Work Plan

Risks Arising Alongside Covid

Billing & Coding Changes

- E/M Coding Changes
  - Office/Outpatient E/M visit level revised for CY 2021
  - Level selected based on either of two methods: “total time” or “medical decision-making”
  - **Compliance Risk**: New rules, big changes, and medical decision-making method is very complex
- 2022 Proposed Rule changes to split/shared visits
- COVID-19 Coding and Billing

2021 E/M Coding Changes

Billing Based on Time or Medical Decision Making (MDM)

- While selecting E/M levels based on time when over 50% of the service consisted of counseling and/or coordination of care has been a long-standing option, 2021 updates allow for billing based on total time without the counseling and coordination of care caveat.
- CMS and the AMA extended the list of provider activities that qualify as time counted towards the level selection. Some newly added activities include preparing to see the patient, ordering medication and documentation.

2021 E/M Coding Changes

Level Selection Based on MDM

- MDM includes establishing diagnoses, assessing the status of a condition, and/or selecting a management option. MDM may be impacted by role and management responsibility.
- In 2021, new policy allows providers to select the level of E/M service based on MDM when documented and accompanied by medically-appropriate patient history and physical exam.
- The MDM table that guides the level selection remains mostly the same with an updated emphasis on the complexities of reviewing and analyzing tests and data.

https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf

2022 PFS Proposed Changes

Split/Shared Services

- Definition of split (or shared) E/M visits as evaluation and management (E/M) visits provided in the facility setting by a physician and an NPP in the same group.
- The practitioner who provides the ***substantive portion*** of the visit (***more than half of the total time spent***) would bill for the visit.
- Split (or shared) visits could be reported for new as well as established patients, and initial and subsequent visits, as well as prolonged services.
- Requiring reporting of a modifier on the claim to help ensure program integrity.
- Documentation in the medical record that would identify the two individuals who performed the visit. The individual providing the substantive portion must sign and date the medical record.
- Allowing Critical Care services be furnished as split/shared.

Orders for COVID-19 Testing

- CMS policies regarding COVID-19 orders during the Public Health Emergency (PHE) have been updated with an important requirement.
  - Initially, during the COVID-19 Public Health Emergency, CMS relaxed billing requirements for laboratory tests required for a COVID-19 diagnosis stating written orders were not required and if an order is not written, an ordering or referring National Provider Identifier (NPI) is not required on the claim.
  - In September 2020, CMS updated this policy stating Medicare patients will receive coverage for one COVID-19 test without an order, but subsequent tests require written orders so patients will receive proper medical attention and oversight for their diagnoses. The policy also reduces billing for unnecessary tests.

https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-05-07-mlnc#_Toc39656771

https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf

Orders for COVID-19 Testing

COVID-19 Orders

- Additionally, CMS policy establishes that any healthcare professional authorized under state law, including pharmacists, may order COVID-19 tests.

- Medicare makes payment for services of pharmacists and certain other healthcare professionals only when they have an arrangement with a physician or other billing practitioner.

- These changes allow Medicare to continue to pay for these tests during the PHE when they are ordered by pharmacists and other healthcare professionals without such an arrangement.

COVID-19 E/M Billing with Testing

E/M with COVID-19 Testing:

- If a patient comes in for an asymptomatic COVID-19 test, the ancillary healthcare staff should screen the patient. If there are no symptoms to indicate illness, the staff should perform the swab and bill a 99211 E/M Code with 99000 supply code.

Per CMS COVID-19 FAQ:

- "Physician offices can use CPT code **99211** when office clinical staff furnish assessment of symptoms and specimen collection incident to the billing professionals services for **both new and established patients**. When the specimen collection is performed as part of another service or procedure, such as a higher-level visit furnished by the billing practitioner, that higher level visit code should be billed, and the specimen collection would not be separately payable."

COVID-19 E/M Billing with Testing

Additionally, when a new patient is billed 99211 for asymptomatic COVID-19 testing, CMS policy allows providers to bill the appropriate new patient category for the subsequent visit.

Per CMS COVID-19 FAQ:

"…under the unique circumstances of the PHE, the patient is not considered an established patient merely due to the reporting of CPT code 99211 for assessment and collection of COVID-19 specimen for a new patient."

COVID-19 E/M Billing with Testing

- If the patient presents for COVID-19 testing and has symptoms, the patient should be assessed by a provider and the appropriate E/M level for the assessment should be applied.
- At this point, the specimen collection 99000 would be considered as part of the E/M and should not be billed separately.
- If the patient was billed as a new patient for this visit, subsequent visits are established patient visits per the usual billing rules.

COVID-19 Testing Codes

Per the CMS FAQ:

If **87635** – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)(Coronavirus disease (COVID-19), amplified probe technique does not describe the services rendered at your office, then **U0002** – 2019-ncov coronavirus, sars-cov-2/2019-ncov (covid-19), any technique, multiple types or subtypes (includes all targets), non-CDC should be utilized.

- The above code should be utilized for symptomatic or asymptomatic patients if the test is performed in the office and not sent out to an external laboratory.

https://www.ama-assn.org/system/files/2020-05/covid-19-coding-advice.pdf

COVID-19 Diagnosis Codes:

- Providers using incorrect diagnosis codes for COVID-19 positive patients may impact the finding of medical necessity for the visit, as well as COVID-19 reimbursement.
- Updated ICD-10 Coding Guidelines for 2021, which went into effect 10/1/2020 are below:
- COVID-19 Diagnosis Codes:
  - **U07.1** – COVID-19 positive (Use additional code to identify pneumonia or other manifestations)
  - **Z20.828** – for asymptomatic/symptomatic individuals with actual or suspected exposure to COVID-19. During a pandemic, screening would be coded as exposure, so even if the individual does not suspect exposure, the exposure code should be reported.

COVID-19 Modifier Application

Modifier CS:

- Providers who bill Medicare Part B services should review use of the CS modifier and ensure that Medicare beneficiaries are not charged a co-payment and/or deductible for services subject to the cost-sharing waiver for COVID-19 testing-related services.
  - This modifier can be appended to both in-person and telehealth services to indicate they are related to COVID-19.
  - If providers fail to append the modifier, then the patient will be erroneously charged their copay/deductible.
  - If this modifier is appended erroneously to non-COVID-19 services, the patient will not be paying their portion of care.

COVID-19 Vaccine and Monoclonal Antibody Infusions Information

- CMS has released a set of toolkits for providers, states and insurers to help the health care system prepare and assist in swiftly administering these products once they become available. These resources are designed to increase the number of providers that can administer the products and ensure adequate reimbursement for administration in Medicare, while making it clear to private insurers and Medicaid programs their responsibility to cover these products at no charge to beneficiaries.

- The coding list of vaccine administrations, drugs, reimbursement amounts and effective dates has grown to be too extensive to share here but can be found on the CMS website.

COVID-19 Vaccine and Monoclonal Antibody Infusions Information

- On November 9, 2020, the U.S. FDA issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy, Bamlanivimab, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization.
  - Since this initial authorization, many drugs have been added and dosages have changed.
  - If your organization is providing these services, be sure that the many changes are being implemented timely.

Compliance Takeaways – Billing and Coding Changes

Policies & Procedures	Training & Education	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
• Review Current Coding and Billing policies and procedures and revise to reflect E/M coding changes for 2021 as well as COVID-19 Coding/Billing	• If not performed already, Providers should be educated on the documentation changes for E/M Services for 2021 • If the proposed PFS rule is implemented, providers should be educated on split/shared coding changes	• Perform Data Analytics on E/M utilization for 2021 • For providers who utilization of high-level E/M codes have increased, perform documentation reviews. • Perform claims reviews on COVID-19 services	• Identify claims with potential overpayments and refund according to CMS/payor guidelines

2021 Stark and AKS Rules: Planning for 2022 Compliance Work Plan

- 2021 Stark and AKS revisions had big impacts:
  - Changes to the "Big 3" (fair market value, commercially reasonable, volume or value of referrals)
  - Relaxations of writing and signature requirements
  - New exceptions & safe harbors
    - Remuneration up to $5,000 (Stark)
    - Outcomes-based payment safe harbor (AKS)
    - Value-Based Enterprises (Stark & AKS)

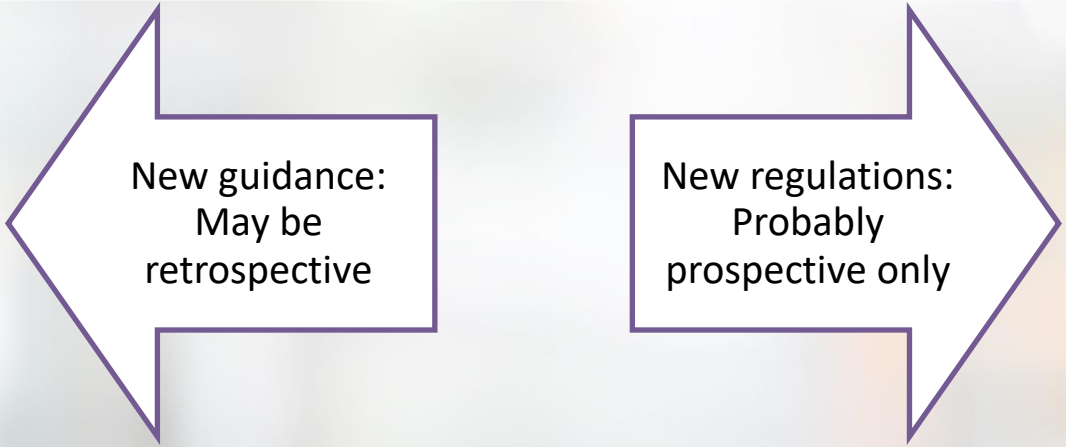
Overview of the 2021 Rules

Concept	Stark	Anti-Kickback
Commercially reasonable	X	
Designated health services	X	
Fair market value	X	
Group practice profit distributions	X	
New exception for reconciling compensation	X	
Volume or value of referrals	X	
Directed referral requirements	X	
Writing requirements	X	
Signature requirements	X	
Exclusive use of leased space or equipment	X	
Physician recruitment exception	X	
Isolated transactions exception	X	
Risk Sharing Arrangements	X	

Concept	Stark	Anti-Kickback
Assistance to compensate NPP exception	X	
New exception for limited remuneration to a physician	X	
Compensation is “set in advance”	X	X
Electronic health records	X	X
Value-based arrangements	X	X
Cybersecurity donations	X	X
Personal services and management contracts safe harbor (addition of outcomes-based arrangements)		X
Warranty safe harbor		X
Local transportation safe harbor		X
Remuneration related to CMS models safe harbor		X
ACO Beneficiary Incentive Program safe harbor		X

Applying 2021 Stark & AKS Rules

- When you find an issue…Which rules apply?
  - Retroactive vs. prospective
  - Changed regulations vs. changed guidance/interpretations
  - Investigations & audits may need to account for differences in applicable rules



Compliance Takeaways – Applying 2021 Stark & AKS Rules

Policies & Procedures	Training & Education	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
• Review and revise policies and procedure and determine whether updates are needed.	• Train workforce on changes to law • Explain why organizational policies and procedures are updated or not updated	• Review and update audit and monitoring tools	• Utilize new rules to determine if conduct violates Stark and AKS (e.g., limited remuneration to a physician exception), as appropriate • During investigations, January 19, 2021 cutoff date will affect analysis and repayment obligations

Value-Based Enterprises

Participants Bear Full Risk	Participants Bear "Meaningful" Risk	Participants Bear Some Risk
• Most flexibility for participants • No "Big Three," no writing requirements…	• 10% risk threshold • Less flexibility • Add writing, set-in-advance, and other requirements	• Least flexibility • Arrangement must be commercially reasonable • Add auditing and monitoring requirements

- **Communicate with leaders**: Compliance should be involved from the very beginning because of the auditing and monitoring expectations
- VBE exceptions/safe harbors have compliance expectations and obligations

No backup exception

Compliance Takeaways – Value-Based Enterprises

Policies & Procedures	Compliance Officer & Committee	Training & Education	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
• Consider developing policies and procedures regarding VBE arrangements.	• CCO may be the one responsible for financial and operational oversight of the VBE.	• Significant training may be required on VBE rules and operations when the organization begins participating in a VBE.	• Organizations are expected, and in some structures, required, to monitor a VBE's compliance with the VBE requirements. • If your organization is in a VBE, VBE compliance should be a regular part of your work plan. You may not have a backup exception/safe harbor!	• Organizations will be breaking new ground when VBE arrangements come under compliance scrutiny. Planning, collaboration, and flexibility will be key.

Opioid Prescribing and Treatment

- Top priority prior to Covid that's been returned to OIG Work Plan
  - Opioid use disorder treatment services provided by opioid treatment programs
  - Opioid use in Medicare Part D in 2020
  - Part B telehealth services (opioid use disorder)
- Complicated area:
  - Medicare/Medicaid rules
  - State law (prescriber scope of practice, prescription drug monitoring, pharmacy practice)
  - DEA requirements
- Eliminating Kickbacks in Recovery Act ("EKRA") a consideration for arrangements involving laboratories and opioid treatment programs

Compliance Takeaways – Opioid Prescribing and Treatment

Policies & Procedures	Compliance Officer & Compliance Committee	Training & Education	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
•Consider including opioid use practices on 2022 Work Plan •Training/Education •Auditing/Monitoring	•Seek education on rules applicable in your state	•Review education materials; ensure prescribers and dispensers are aware/reminded of rules on prescribing & dispensing controlled substances	•Include prescriptions for opioids in claims reviews	•Comprehensive approach needed for resolving any noncompliance involving opioid prescribing & dispensing

Pre-Covid Risk Assessments & Work Plans

- Pre-Covid Risk Assessments
  - What did the organization identify as a risk going into 2020?
  - Is it still a risk?
- Pre-Covid Work Plans
  - What projects did the organization begin or plan going into 2020?
  - Does the work need to be revived?

Compliance Takeaways – Pre-Covid Risk Assessments & Work Plans

Policies & Procedures	Compliance Officer & Compliance Committee	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
• Consider adding review of existing risk assessments/ work plans to 2022 Work Plan	• Evaluate existing risk assessments & work plans to identify current risks	• Re-engage in auditing/monitoring areas for areas considered “solved” shortly before Covid	• Carefully evaluate noncompliance and determine if root causes other than Covid need to be addressed

Compliance Takeaways – Summary

	Policies & Procedures	Compliance Officer & Committee	Training & Education	Auditing & Monitoring	Identifying Noncompliance & Corrective Action
PRF Data Reporting	X	X	X	X	
Covid Uninsured Program	X		X	X	X
Telehealth	X		X	X	X
Waivers	X	X	X	X	
Coding Changes	X		X	X	X
2021 Stark & AKS Rules	X		X	X	X
Value-Based Enterprises	X	X	X	X	X
Opioids	X	X	X	X	X
Existing Work Plans & Risk Assessments	X	X		X	X

Questions?

For more information on these topics visit hallrender.com.

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