# **Regulatory 411:**

# PA Practice, Compliance, and Regulatory Updates

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- This presentation was current at the time it was submitted.
- Although every reasonable effort has been made to assure the accuracy of the information herein, the ultimate responsibility for the correct submission of claims and response to any remittance advice lies with the provider of services. The provider must ascertain payment policy and claims methodology for each payer with whom they contract.

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# **Objectives**

- Define scope of practice and appraise determinants of scope of practice
- Describe Federal legislation and Centers for Medicare and Medicaid Services policies related to PA practice and reimbursement
- Discuss implications of fraud and abuse in healthcare







# **Medicare Conditions of Coverage & Participation**

### **Conditions for Coverage**

- Conditions that must be met to lawfully request and receive Federal healthcare funds
- Apply to beneficiaries

### **Conditions of Participation**

- Conditions that must be met to participate in and receive funds from a Federal health care program
- Typically relate to the quality of care provided
- May apply to non-beneficiaries

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# **Implied Certification**



Submission of claim "certifies" compliance with all conditions of participation and conditions for coverage



If a healthcare provider or organization is out of compliance with a State or Federal statute, CMS regulation, or accreditation standard = basis for false claims

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# The following must be met to submit a claim for Federal reimbursement

Federal Statutes & Regulation

State Statutes & Regulations

Accreditation Standards

Hospital Policies & Bylaws

Scope of Practice & Privileges

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# Medicare & PAs

//www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Do

"If authorized under the scope of their State license, PAs may furnish services billed under all levels of CPT evaluation and management codes, and diagnostic tests"

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# Medicare & PAs

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

Services of a PA may be covered, if all requirements are met:

- Performed by a person who meets all PA qualifications
- Type that are considered physicians' services if furnished by a doctor of medicine or osteopathy
- Are performed under the general supervision of an MD/DO
- Legally authorized in the state in which they are performed
- Not otherwise precluded from coverage because of a statutory exclusion

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# Examples of PA Services

New & Established Outpatient Visits

Initial & Subsequent Hospital, Discharge and Observation Services

Critical Care & Emergency Department Services

Minor Surgical Procedures and Assistant-At-Surgery Services

**Diagnostic Tests and Interpretations** 

Chronic Care Management

**Telehealth Services** 

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- Graduated from a physician assistant educational program that is accredited by the ARC-PA (or its predecessor agencies)
- Passed the national certification examination that is administered by NCCPA

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• Be licensed by the State to practice as a PA

tps://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

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# PA Direct Pay Bill (S. 596 / H.R. 1052)

Inability to receive direct pay adversely affects PAs:

- Practicing in certified rural health clinics
- Working in a medical group that contracts with a hospital

Wanting to own their own clinic

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# When State law does not require "supervision"...

- > 10 states and the District of Columbia use terms other than supervision
  - Several states use "collaboration"
  - Michigan uses "participating physician"
- At least one state (North Dakota) has no defined relationship between a PA and physician
- Medicare has new policy that largely defers to state law on how PAs practice with physicians and other members of the health care team

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# When State law does not require "supervision"...

"We believe that, in the absence of state law, if there is documentation at the practice which demonstrates the working relationship that PAs have with physicians in furnishing their professional services, then this would be adequate to ensure that the statutory requirement for PA physician supervision is met."

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ederal Register / Vol. 84, No. 221 / Friday, November 15, 2019 / Rules and Regulations (pages 62678-62681)

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# **Restraint & Seclusion**

Prior to December 2019 Medicare Conditions of Participation stated:

§ 482.13(e)(5) use of restraint or seclusion must be in accordance with the order of a physician or <u>licensed independent practitioner</u> who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law

> **Licensed Independent Practitioner** An individual authorized to provide care and services without direction or supervision

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# **Restraint & Seclusion**

- CMS changed term
  "Licensed Independent Practitioner" to
   "Licensed Practitioner
- Effective November 29, 2019
- Resulted from ongoing
  AAPA advocacy

482.13(e)(5) use of restraint or seclusion must be in accordance with the order of a physician or other <u>licensed practitioner</u> who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law

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### NEW Joint Commission Elements of Performance Effective 3/15/20

### PC.03.05.05

The hospital initiates restraint or seclusion based on an individual order.

# **Elements of Performance for PC.03.05.05**

1. A physician, clinical psychologist, or other authorized licensed independent practitioner primarily responsible for the patient's ongoing care orders the use of restraint or seclusion in accordance with hospital policy and law and regulation.

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# **Restraint & Seclusion**

For PAs to order restraint and the following criteria must be met:

- Consistent with hospital bylaws and policies
- Included as part of a PA's scope of practice, practice agreement, and granted privileges
- Not prohibited by State laws or regulations



# Hospice – PAs as "Attending Physician"

# Before Jan 1, 2019

- PAs not permitted to provide care directly related to a hospice patient's terminal illness
- Physicians and NPs able to provide and be reimbursed for these services

# After Jan 1, 2019

- Medicare definition of hospice "attending physician" broadened to include PAs
- PAs permitted to provide, manage, be reimbursed by Medicare for hospice services

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### **PAs and Hospice** Certify Terminal Illness Serve as Hospice Attending Physicians Conduct Face-to-Face Visit for Recertification (if needed) Order Medications for Hospice Beneficiaries (no restrictions) Serve as Hospice Attending Physicians Conduct Face-to-Face Visit for Recertification (if needed) & NPs Order Medications for Hospice Beneficiaries (no restrictions) Serve as Hospice Attending PAs Order Medications for Hospice Beneficiaries with Restrictions AARA © Ame

# PAs and Hospice

To order medications for a Medicare hospice beneficiary, a PA must:

- Be serving as a patient's "attending physician"
- Not an employee of, or under arrangement with, the hospice

tps://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf?utm\_source=federalregister.gov&utm\_medium=email&utm\_campaign=pi+subscription+mailing+list

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# **Durable Medical Equipment**

- PAs authorized to order and certify necessity for DME
- Certain DME require face-to-face encounter within 6 months of order
  - PAs authorized to perform face-to-face encounter

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Medicaid was unclear

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# **Durable Medical Equipment**

- No stand-alone category for DME in Medicaid statute
  - Only mention of DME is under Home Health section
  - Since Home Health could only be ordered by a physician, an increasing number of state Medicaid programs interpreted DME to require a physician order
- Statutory and Regulatory Fix
  - CARES Act & COVID-19 Public Health Emergency Interim Rules
  - Authorized PAs (and NPs) to order/certify Home Health & DME for Medicaid beneficiaries AARA

https://www.cms.gov/files/document/covid-final-ifc.pdf

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# **Student Documentation**

### **Former CMS Policy**

Only teaching <u>physicians</u> could use documentation in the medical record made by <u>medical students</u>

### New CMS Policy (January 1, 2020)

Physicians, PA and APRNs may review & verify, rather than redocument, information recorded by:

- Medical students, residents, and physicians
- PA and APRN students
- Other members of the medical team

ttps://www.cms.gov/newsroom/fact-sheets/finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar

# **Student Documentation**

### **Caveats & Best Practices**

- Must be allowed by hospital/facility policy
- Provider submitting claim for service should:
  - Personally examine & evaluate patient
  - Review & verify accuracy of student documentation
  - Sign & date note (with necessary, if any, updates to documentation)

May require changes to existing EHR software & programming 

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# **EMTALA**

- Ensures access to emergency services regardless of ability to pay
- Requires medical screening examination (MSE) of emergency medical condition (EMC)
- Must provide stabilizing treatment of EMCs
- Must arrange appropriate transfer if not capable of providing stabilizing treatment or if patient requests

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# **EMTALA**

ttps://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/Downloads/CMS-1063-F.pdf © Americ ttps://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-15.pdf

- Hospitals must maintain a list of physicians who are on call to provide treatment necessary to stabilize an individual with an EMC after initial examination
- If a physician on the list is called to provide emergency screening or treatment and fails or refuses to appear within a reasonable period of time, the hospital and physician may be in violation of EMTALA

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### **False Claims Act**

s://www.govinfo.gov/content/pkg/USCODE-2010-title31/pdf/USCODE-2010-title31-subtitleIII-chap37-subchapIII-sec3729.pdf

Imposes civil liability on "any person who **knowingly** presents, or **causes** to be presented a false or fraudulent claim for payment."

*Knowingly* means a person has "actual knowledge of the information", acts in "**deliberate ignorance**", or **reckless disregard**" of the truth or falsity.

"No proof of specific intent to defraud is required to violate the civil FCA."



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# **False Claims Act**

ttps://www.govinfo.gov/content/pkg/FR-2018-01-08/pdf/2017-28230.pdf

In addition to refunding payments and costs to the Federal government for civil action:

Treble damages (up to 3X amount violator received)

Civil monetary penalties (up to \$22,363 per false claim)

Additional fines and/or imprisonment

Exclusion from Medicare, Medicaid, and all other Federal healthcare programs

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### **Anti-Kickback Statute**

ttps://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1734B3.pdf

- Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals that generate Federal health care program business
- False Claims Act liability, criminal fines, civil monetary penalties, prison term (up to 5 years per violation), exclusion from Federal programs

### **Stark Law**

https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1734B3.pdf

- AKA 'Physician Self-Referral Statute'
- Prohibits a physician from referring Medicare patients for health services to an entity with which the physician (or immediate family member) has a financial relationship
- Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
- False Claims Act liability, civil monetary penalties, exclusion from Federal programs

Law specifically applies to physicians; implications for PAs, who are advised to follow law as if it directly applies to them

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### Federal Health Care Fraud Statute 18 USC 1347

- "Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice to defraud any <u>health care benefit</u> <u>program</u>..."
  - "any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual"
- •Under the federal constructive knowledge standard, if a person should have knowledge had he or she made "usual and proper inquiries", this can be enough to establish knowledge in some cases.

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# <section-header> Federal Health Care Fraud Statute 18 USC 1347 Fines \$250,000 (for individuals) \$500,000 (for organizations) Sponson (general offenses) 10 years (general offenses) 20 years (fraud results in serious bodily injury) Life sentence (fraud results in death)

### DOJ "Yates Memo"

- Subject: Individual Accountability for Corporate Wrongdoing
- From: Deputy Attorney General, Sally Quillian Yates
- Date: September 9, 2015

"Fighting corporate fraud and other misconduct is a top priority of the Department of Justice."

"One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing."

"The Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation."

https://www.justice.gov/archives/dag/file/769036/download

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### **Since Yates Memo**

 Sentences for healthcare fraud offenders with a leadership or supervisory role in the offense:

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- ↑ 22.0% in FY 2015
- ↑ 19.9% in FY 2016
- ↑ 26.8% in FY 2017
- Punishment (in FY 2017)

https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Health\_Care\_Fraud\_FY15.pdf https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Health\_Care\_Fraud\_FY125.pdf https://www.ussc.gov/sites/default/files/pdf/research-and-publications/quick-facts/Health\_Care\_Fraud\_FY127.pdf

- 80.3% of offenders sentenced to imprisonment
- Average sentence was 37 months

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<b>600+</b> whistleblower cases each year	<b>\$2.1 of \$3</b> billion in FCA settlements from whistleblowers in 2019	<b>30%</b> of recovered funds eligible to whistleblowers
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# **EHR Fraud Vulnerabilities**

Allegations against CareWell

- Used EHR templates and other methods to document more than medically necessary and cause submission of "inflated and upcoded claims to Medicare"
- "engaged in a calculated scheme to reap unjustified economic benefit for their own gain"



//www.iustice.gov/usao-ma/pr/ca

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### **EHR Fraud Vulnerabilities**

- Safeguarding against use of EHR in fraud and abuse top priority of CMS & OIG
- Cloning, copy & paste, auto-fill, macros, pre-populated templates
  - Subject of targeted probes

nttps://oig.hhs.gov/cejr/reports/aei-01-11-00570.pdf
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ttps://oig.hhs.gov/reports-and-publications/compendium/files/compendium2018.pdf
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 May be considered failure to meet documentation of medical necessity, lead to recoupment of payments for services, and be considered fraud

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JUSTICE NEWS Department of Justice			
			Office of Public Affairs
FOR IMMEDIATE RELEASE	Tuesday, October 21, 201		
	ced to 15 Years in Prison for \$200 Million raud Scheme		
A Miami licensed physician assistant was sentenced today to scheme involving approximately \$200 million in fraudulent t health company that was headquartered in Miami.	serve 15 years in prison for participating in a Medicare fraud pillings by American Therapeutic Corporation (ATC), a mental		
of the Southern District of Florida, Special Agent in Charge G	epartment's Criminal Division, U.S. Attorney Wifredo A. Ferre eorge L. Piro of the FBI's Miami Field Office and Special Agent Office of Inspector General's (HHS-OIG) Florida region made		

JUSTICE NEWS			
Office of Public Affairs			
FOR IMMEDIATE RELEASE	Wednesday, September 18, 2019		
	viduals for Alleged West Coast Medicare and Medicaid chemes Totaling \$258 Million		
care fraud enforcement action in the state of Ca	ki of the Justice Department's Criminal Division announced today a health lifornia, involving charges brought against a total of 26 individuals in the volvement in Medicare and Medicaid fraud schemes resulting in \$257		
,,	ia, Keyvan Amirikhorheh, M.D., 60, of Seal Beach, California, Lorrain illage, California, Noem Sarkisyan, 63, of North Hollywood, California		

**Department of Justice** U.S. Attorney's Office

Eastern District of Pennsylvania

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FOR IMMEDIATE RELEASE

ttps://www.justice.gov/usao-edpa/pr/fourteen-individuals-charged-operating-pill-mills-and-illegally-prescribing-drugs

Wednesday, February 6, 2019

### Fourteen Individuals Charged for Operating "Pill Mills" and Illegally Prescribing Drugs to Hundreds of Patients in Multiple Locations in the Philadelphia Area

70, of Elkins Park, PA; Dr. Frederick Reichle, 83, of Warrington, PA; Dr. Marcus Rey Williams, 70, of Coatesville, PA; Dr. William Demedio, 58, of Springfield, PA; Dr. Neil Cutler, 77, of Warminster, PA; Physician's Assistant Mitchell White, 33, of Philadelphia, PA; Physician's Assistant Jason Dillinger, 40, of West Chester, PA; Physician's Assistant Debra Cortez, 56, of Bristol, PA; Physician's Assistant Samantha Hollis, 42, of Wilmington, DE, and Office Manager Joanne Rivera, 35, of Pennsauken, NJ. Each defendant Hollis, 42, of Wilmington, DE, and Office Manager Joanne Rivera, 35, of Pennsauken, NJ. Each defendant Hollis, 42, of Wilmington, DE, and Office Manager Joanne Rivera, 35, of Pennsauken, NJ. Each defendant Hollis, 42, of Wilmington, DE, and Office Manager Joanne Rivera, 35, of Pennsauken, NJ. Each defendant Hole and Provide Hole Control and Content of the Provide Hole Conten

"Healthcare providers who ignore their Hippocratic oaths and put illegal prescription drugs on our streets are nothing more than **drug dealers in white lab coats**," said Maureen R. Dixon, Special Agent in Charge of the Philadelphia Regional Office of the Inspector General for the Department of Health and Human Services (HHS-OIG). "Medical providers who disregard the law and put greed in front of helping patients can expect criminal repercussions."

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# Ryan Haight Online Pharmacy Consumer Protection Act

- Federal law enacted in 2008
- Created to regulate internet prescriptions
- Prohibits providers from prescribing controlled substances to patients they have not examined in person

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://www.govtrack.us/congress/bills/110/hr6353/t

### **Overlapping Surgery**

//www.finance.senate.gov/imo/media/doc/Concurrent%20Surgeries%20Report%20Final.pdf

- Physician must be physically present during all critical or key portions of the procedure and be immediately available during the entire procedure
  - Those in which the essential technical expertise and surgical judgment of the surgeon is required to achieve an optimal patient outcome (ACS)
  - Opening and closing of surgical site is generally not critical (CMS & ACS)

Hospitals should have policies regarding overlapping surgeries and safeguards to prevent concurrent surgeries.

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### Whistle-blower files suit over alleged double-booked surgeries by Jonathan Saltzman and Todd Wallack Boston Globe

Orthopedic surgeons at Massachusetts General Hospital repeatedly kept patients waiting under anesthesia longer — sometimes more than an hour longer — than was medically necessary or safe, as they **juggled two or even three simultaneous operations**, according to a federal lawsuit that alleges frequent billing fraud at the prestigious hospital.

Dr. Lisa Wollman, a former anesthesiologist at Mass. General, alleges in the lawsuit that at least five surgeons endangered patients by regularly performing simultaneous surgeries. Wollman charges that the doctors also **defrauded the** government by submitting bills for surgeries in which they were not in the operating room for critical portions of procedures, leaving the work to unsupervised trainees.

while-they-did-se









aiting-under-anesthesia-while-thev-did-second-surgeries-whistle-blower-charges/OshFeHhRn92WOSwDEli1LO/story.htm



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# U.S. attorney investigating DMC over possible federal anti-kickback violations

by Jay Greene Crain's Detroit Business

... termination of the employment of 14 nurse practitioners and physician assistants was due, in part, to the company's concerns that their prior employment did not comply with the Anti-kickback Statute, the Stark law and False Claims Act.

... services the NPs and PAs were delivering to private doctors might run afoul of federal laws designed to prevent improper patient referrals to the hospital.

... blatant violations would be a hospital paying fees for admissions or services, but could also include offering doctors office leases at below market value, or free or discounted services like advanced-practice providers' coverage of private doctors' patients.

vs/654046/us-attornev-investigating-dmc-over-possible-federal-anti-kickback



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... agreed to pay \$528,158 for allegedly **violating** the Civil Monetary Penalties Law **provisions applicable to kickbacks and physician self-referrals**.

The OIG alleged that Inova **paid remuneration** to Arrhythmia Associates (AA) **in the form of services provided by certain PAs within the office of AA**. Specifically, Inova provided PA service to AA without written contract in place and failed to bill and collect for those PA services.

it-self-disclosed-conduct-to-the-OIG-Inova-Health-Care-Serv





nd-returning-self-identified-o

- Consult with compliance and in-house counsel
- Follow Provider Self-Disclosure protocol
  - Opportunity to minimize penalties and fines
- Report and return "overpayments"
  - Obligation to:

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- report and return funds from the past 6 years
- that a person or organization is not entitled
- within 60 days of identifying the overpayment
- Failure to do so is liable to False Claims Act penalties

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### **Additional References & Resources**

- Medicare Claims Processing Manual
  - Chapter 12 Physicians/Nonphysician Practitioners

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf

Chapter 15 – Covered Medical and Other Health Services

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

### Code of Federal Regulations

Title 42 – Public Health

https://www.ecfr.gov/cgi-bin/textidx?SID=28cbafbbd980d94723375b715d900a73&mc=true&tpl=/ecfrbrowse/Title42/42tab\_02.tpl

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