Challenges and Legal Issues in Telemedicine Programs

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Challenges and Legal Issues in Telemedicine Programs

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Current Industry Trends

- Telemedicine is an immensely fast growing section of healthcare.
- Healthcare providers are investing substantial amounts of money into telemedicine.¹
- In 2014 the telemedicine market stood at $17.8 billion and is expected to grow at 18.4% between 2014 and 2020.²
- U.S. employers could save up to $6 billion per year by providing telemedicine technologies to their employees.³
How Telemedicine is Being Used

- **Store-and-Forward**: Data is sent to a specialist for review after it has been acquired from the patient. Physician does not need to actually meet the patient. This is frequently seen in radiology.
- **Remote Monitoring**: Uses technology devices to monitor health of patients remotely. Commonly used in ICUs.
- **Real-Time Interactive Services**: Consultation and assessment done over the phone or on video. Usually used in psychology, but can also be used for diagnosis of common illnesses and for physical therapy treatment.

Legal Background

- Prior to 2011, Centers for Medicare and Medicaid Services (CMS) required all hospitals to fully credential professionals providing telemedicine services.
- However, many facilities were only complying with the less strict standards set by The Joint Commission (TJC) which did not necessarily meet the Conditions of Payment requirements (CoP) set forth by CMS.¹
- As a result, CMS issued new guidelines allowing for credentialing and privileging by proxy.²
- The new rules went into effect July 5, 2011.³

Why Change the Rule?

- CMS’s final rule allows for the expansion of telemedicine.
- This benefits remote and rural area hospitals, giving them access to larger hospital system’s physicians.
- Patients may be able to receive quicker access to appropriate medical care.
- By allowing privileging by proxy, healthcare providers can cut cost and time associated with the lengthy credentialing and privileging process.
Relevant Laws and Regulations

- CMS-Changes were placed in the hospitals Conditions of Participations (CoPs) regulations:
  - 42 CFR § 482.12
  - 42 CFR § 482.22
  - 42 CFR § 485.616

- TJC-Rules mimic the regulations by CMS:
  - LD.04.03.09
  - MS.13.01.01

Three Options for Credentialing

- Complete credentialing of all telemedicine providers by the host site. This is the most time intensive and costly.
- Rely on the credentialing and privileging performed by other Medicare certified hospital
- Rely on the credentialing and privileging decisions of other telemedicine entities.

What is a “Telemedicine Entity”?

“[A] distant-site telemedicine entity is defined as an entity that –
(1) provides telemedicine services;
(2) is not a Medicare-participating hospital; and
(3) provides contracted services in a manner that enables a hospital or [critical access hospital] CAH using its services to meet all applicable Conditions of Participation (CoPs), particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of the hospital or CAH.”

Source: http://thetelemedicinedirectory.com/lc/telemedicine-law/

Sample Telemedicine Entities

Growing Telehealth Options – On-Demand Medicine

Source: TrialHealth carded list of telehealth companies, 24 September 2015

Overview of State Licensure

- States are responsible for regulating and monitoring health care professionals within their boundaries.
- Licensure rules apply to all health care professionals, including those who practice telemedicine within states and across different states.
- Traditional state licensure rules can be difficult to square with telemedicine, which transcends geographic boundaries.
- Health professionals who practice telemedicine without a proper state license risk criminal as well as civil penalties, and state disciplinary proceedings. Additionally, some medical malpractice insurance policies may deny coverage during a lawsuit because they require licensure as a condition of coverage.¹

State Licensure

- Most states require the health care professional to be licensed in the state they are practicing, however some states offer reciprocity or licensure portability.
- The American Telemedicine Association publishes a report card for each state, grading them from A to F, on the reasonableness of its telemedicine practice standards, licensure requirements, and policy on Internet prescribing.

State Licensure

Most states have enacted legislation requiring providers using telemedicine technology across state lines to have a valid state license in the state where the patient is located.

- 49 states (excluding NY) and the District of Columbia require full medical licensure to provide direct care.\(^1\)
- 10 states have a special telehealth, conditional, or special purpose license to practice telemedicine.\(^2\)
- DC, MD, NY and VA are the only states that permit licensure reciprocity from bordering states.\(^3\)
- 12 states have signed a FSMB Compact that requires an expedited licensing process for out-of-state practitioners.\(^4\)

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State Ratings – Licensure and Out-of-State Practice

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States Requiring a Specific Telemedicine License

- Alabama
- Louisiana
- Maine
- Minnesota
- Nevada
- New Mexico
- Ohio
- Oregon
- Tennessee
- Texas
International Telemedicine

- Telemedicine services are not only provided in the United States, but are now expanding beyond our borders.¹
- Pathology and Radiology are the two most common international services.²
- State law still applies to international distant-site providers who will be providing services in that state.
- Even if the provider is licensed in the proper state, this cannot create communication issues.
  - What if the distant-site provider cannot be reached?
  - What if there is a language barrier?
  - What if there is a extreme disaster that cuts off communication with the distant-site or there is a technology failure?

Licensure: Exceptions

- **Endorsement**
  - Allows out of state licensed physicians to obtain in-state licenses based on out-of-state credentials rather than going through initial licensure process.¹
- **Registration**
  - Allows out of-state licensed physicians to register with in-state medical licensing boards rather than obtaining an additional license.²
- **Reciprocity**
  - Specific agreements between state licensing boards to mutually recognize out-of-state licenses.³
- "**Border States**" Exception
  - Permits in-state practice out of medicine by out-of-state physicians licensed in bordering areas.⁴

Physician-to-Physician (P2P) Exemptions

- Every state provides for some type of exemption for provider-to-provider consultations but these descriptions can vary from state to state. For Example:
  - **Oregon**: A license to practice across state lines is not required of a physician:
    (a) Engaging in the practice of medicine across state lines in an emergency (ORS 677.060 (3)), or
    (b) Located outside this state who consults with another physician licensed to practice medicine in this state, and who does not undertake the primary responsibility for diagnosing or rendering treatment to a patient within this state;
    (c) Located outside the state and has an established physician patient relationship with a person who is in Oregon temporarily and who requires the direct medical treatment by that physician.¹
  - **Arizona**: A doctor of medicine residing in another jurisdiction who is authorized to practice medicine in that jurisdiction, if the doctor engages in actual single or infrequent consultation with a doctor of medicine licensed in this state and if the consultation regards a specific patient or patients.²
Scope of Practice

- The most common concern in telemedicine scope of practice issues is remote prescribing.
- States have varying approaches:
  - Some require in person evaluation or exam before prescribing
  - Some only permit physicians to prescribe via telemedicine technologies if there is a preexisting physician/patient relationship
  - Often, these regulations require a “valid patient relationship” which is defined elsewhere in the state's code or medical boards regulations.
- Many states prohibit prescribing based solely on information gathered from an online questionnaire.

Example: “Pharmacists are prohibited from dispensing prescription drugs if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consult, or a telephone consult, and was completed without a pre-existing patient provider relationship.”

Written Agreement

- “The governing body must ensure that, when telemedicine services are furnished to the hospital, the agreement is written.”
- This applies to both Medicare certified distant-site hospitals and distant-site telemedicine entities.
- The contract must contain a provision stating that it is the responsibility of the distant-site hospital or telemedicine entity to ensure they meet the CoP:
  - For Medicare participating hospital sites this is 42 CFR § 482.12(a)(1)-(a)(7)
  - For CAHs this is in 42 CFR § 485.616(c)(1)-(c)(7)

Written Agreements for Hospitals

- Federal law differentiates between a Medicare participating hospital and a CAH site.
- The law then separates agreements between distant-site hospitals and distant-site telemedicine entities.
- However, even though the requirements are found in different sections of the code, they are nearly identical for both Medicare participating hospitals and CAHs.
What Should the Written Agreement Contain?

If you are a hospital contracting with a distant-site hospital 42 C.F.R. § 482.22(a)(1):
(i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital.
(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which permits a current list of the distant-site physician or practitioner's privileges at the distant-site hospital to be transmitted to the hospital whose patients are receiving the telemedicine services, which provides a current list of the distant-site physician or practitioner's privileges at the distant-site hospital to the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the distant-site physician or practitioner. As a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients and all complaints the hospital has received about the distant-site physician or practitioner.

If you are a hospital contracting with a distant-site telemedicine entity 42 C.F.R. § 482.22(a)(2):
(i) The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).
(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which permits a current list of the distant-site physician or practitioner’s privileges at the distant-site hospital to be transmitted to the hospital whose patients are receiving the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital.
(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital is located.
(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the distant-site physician or practitioner. As a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients and all complaints the hospital has received about the distant-site physician or practitioner.

If you are a hospital contracting with a distant-site telemedicine entity 42 C.F.R. § 482.22(a)(2):
(i) The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).
(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which permits a current list of the distant-site physician or practitioner’s privileges at the distant-site hospital to be transmitted to the hospital whose patients are receiving the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital.
(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital is located.
(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site hospital such information for use in the periodic appraisal of the distant-site physician or practitioner. As a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients and all complaints the hospital has received about the distant-site physician or practitioner.

What Should the Written Agreement Contain?

If you are a CAH contracting with a distant-site telemedicine entity 42 C.F.R. § 485.616(c)(4):
(i) The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at paragraphs (c)(1)(i) through (c)(1)(vi) of this section.
(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which permits a current list of the distant-site physician or practitioner’s privileges at the distant-site hospital to be transmitted to the hospital whose patients are receiving the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital.
(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the CAH is located.
(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the CAH’s patients’ and all complaints the CAH has received about the distant-site physician or practitioner.

If you are a CAH contracting with a distant-site hospital 42 C.F.R. § 485.616(c)(3):
(i) The distant-site hospital providing telemedicine services is a Medicare-participating hospital.
(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which permits a current list of the distant-site physician or practitioner’s privileges at the distant-site hospital to be transmitted to the hospital whose patients are receiving the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital.
(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital is located.
(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the hospital such information for use in the periodic appraisal of the distant-site physician or practitioner. As a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients and all complaints the hospital has received about the distant-site physician or practitioner.

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When to Amend Your Written Agreement

- Written agreements can have an amendment clause:
  - “Amendment: This Agreement may only be amended by the mutual written consent of the Parties.”
- Require notification if the distant-site provider subcontracts telemedicine services
- If the written agreement renews automatically, review it near the end of the term.
- Major leaps in technology
- If there are any changes in state or federal law

Physician Patient Relationship: Telemedicine Informed Consent

**DO's**

1. Know the legal requirements in the jurisdiction
2. Understand the form is mere evidence
3. Verify identity of the signer
4. Point out limitations of the technology used

**DON'Ts**

1. Re-purpose a form developed for in-person care
2. Overstate benefits or understate risks
3. Allow patient to sign without discussing and assuring his/her understanding of risks
4. Promise complete, absolute security

Informed Consent for Telemedicine Services

I understand that any health care professional (telehealth) may participate in a telemedicine consultation at [name of facility]. Specifically, I understand that:

1. Telemedicine involves the electronic exchange of medical information from one site to another using real-time audio and visual communication technology to provide patient care in a safe, effective, and ethical manner, consistent with the standards of medical practice, to enhance access to medical care for patients.
2. The health professional conducting the telemedicine consultation is responsible for the quality of the consultation and for the provision of the care that they would deliver in-person.
3. To the extent permitted by law, patients have the right to refuse to be consulted by a telehealth professional.
4. The rights and responsibilities of patients and health professionals are consistent with the standards of medical practice.
5. To the extent permitted by law, patients have the right to refuse to be consulted by a telehealth professional.
6. The health professional conducting the telemedicine consultation is responsible for the quality of the consultation and for the provision of the care that they would deliver in-person.
7. To the extent permitted by law, patients have the right to refuse to be consulted by a telehealth professional.
8. The rights and responsibilities of patients and health professionals are consistent with the standards of medical practice.
9. To the extent permitted by law, patients have the right to refuse to be consulted by a telehealth professional.
10. The rights and responsibilities of patients and health professionals are consistent with the standards of medical practice.

Physician: 

Patient: 

Informed consent was discussed. 

Patient's Signature: 

Date: 

[If authorized sign, relationship to patient:]

Interpreter's Attestation (where applicable):
Consent Issues

- What if the patient will not sign the consent form?
- What is the difference between P2P consultation and consent to care?
- Where should the informed consent form be kept?
- What if a patient does not sign an informed consent form and telemedicine services are provided anyway?
- Do emergency situations preclude the need for a signed informed consent form?

Avoiding Technology Issues

- When addressing technology liability make sure to address:
  - Who is liable for equipment failures and repair.
  - Distant-sites compliance with regulatory standards. (HIPPA/FDA/FTC/FCC/ONC)
  - Who will provide training for the technology?
  - Will the equipment be updated or upgraded on a regular schedule and who will be responsible for this?

- Additionally, there are concerns about who is liable if a technology issue results in a breach of security or patient injury.
  - What if a person at the originating hospital hacks into the distant-sites EHR system?
  - Conversely, what if the distant-site is infiltrated by ransomware and patient information from the original site is leaked?
  - Where and who is responsible for backend server support?
  - What happens if, due to a ransomware attack, the distant-site is not able to provide any telemedicine services for several days?
  - Written agreements should contain an indemnification clause to reduce these disputes.
Sample Technology Agreement

Monitoring Performance

• “The hospital or CAH must, under the terms of the agreement, review the services provided to its patients by telemedicine physicians and practitioners covered by the agreement and provide written feedback to the distant-site hospital or telemedicine entity, addressing, at a minimum, all adverse events or complaints related to the telemedicine services provided at the hospital or CAH.”

• At a minimum, this information must include:
  • all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients; and
  • all complaints the hospital has received about the distant-site physician or practitioner.

Monitoring Performance

• The Hospital or CAH should keep a record of who is privileged at their site in order to monitor performance.
  • Develop a policy concerning how often this will be reviewed and updated.
  • Hospitals and CAHs should set policies on what information to collect and when to notify the distant-site provider:
    • How much information will be shared?
    • Are the physicians added to the quality review process?
    • Will the process be different depending on the type of provider (Radiologist/Nurse/PA)?
    • Are providers added to peer review process?
    • How are providers addressed in the hospital bylaws?
    • Will the distant-site also be doing periodic reviews?
Telemedicine Malpractice Litigation

- Thankfully, the number of malpractice lawsuits involving telemedicine has been small.  
- Jonathan Linkous, CEO of the American Telemedicine Association: "People have sued hospitals because they didn’t use telemedicine…[t]he claim was that this is now the standard of care."  
- However, some states have enacted “long-arm” statutes that allows lawsuits to be brought against a medical practitioner in the state where the patient was treated. This could create expensive litigation and concerns over choice of law.

Negligent Credentialing Liability

- States have varying laws regarding the ability to bring a lawsuit due to negligent credentialing. These lawsuits can be extremely costly.  
- Often, telemedicine business disputes are perfect for mediation and alternative dispute resolution. Is this covered in your written agreement?  
  - Who maintains coverage for professional liability?  
  - What is the amount of coverage?  
  - Does the distant-site have to provide updates or notice of any changes to it’s insurance?

Beyond CMS and TJC, Best Practices:

- Control your own credentialing process.  
- Written agreement should have:  
  - Clear definitions  
  - Strategy for where telemedicine fit into hospital bylaws  
  - Strong indemnification clause  
- Recommended Policies:  
  - Federation of State Medical Boards published a “Model Policy for the Appropriate use of Telemedicine technologies in the Practice of Medicine.”  
  - Consider what will happen if the distant-site provider no longer meets the standards set forth in the written agreement.  
  - Who will train the hospital staff on telemedicine policies?
Case Study

- A rural Tennessee hospital, “Tennessee Community Hospital” (TCH), wants to provide telemedicine services at its hospital.
- **Step 1**: TCH must first decide if they will contract with a distant-site hospital or distant-site telemedicine entity.
- **Step 2**: Decide if TCH will be conducting the credentialing and privileging or if they will rely on the distant-site provider.
- **Step 3**: TC should be aware of any state laws effecting the scope of practice, licensure and informed consent.

Scope of Practice

**Scope of Practice**: Tennessee has generally, more liberal prescribing laws. Per Tenn. Comp. R. & Reg. R. §0880-02-.14, a physician may prescribe as long as they have done all of the following:

1. Performed an appropriate history and physical examination; and
2. Made a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care; and
3. Formulated a therapeutic plan, and discussed it, along with the basis for it and the risks and benefits of various treatment options, a part of which might be the prescription or dispensed drug, with the patient; and
4. Insured availability of the physician or coverage for the patient for appropriate follow-up care.

Informed Consent

**Informed Consent**: The individual being evaluated via telehealth must be informed of the process and given an opportunity to request an in-person face-to-face assessment before conducting a telehealth assessment. This should be documented in his/her record.

A) Explanation of the process shall include a statement that services will not be withheld if the telehealth encounter is refused and the individual may terminate the telehealth assessment at any time.

B) Documentation must contain a statement that the telehealth process was explained to the individual and whether or not an objection was raised.”
Licensure

- Currently, Tennessee requires a special license for anyone who is practicing telemedicine "within" Tennessee.¹
- This requires:²
  - A check or money order for $410
  - An 8 page application
  - A clear and recognizable photograph
  - A notarized copy of a specialty certification from a recognized specialty
  - Proof of citizenship in the United States, Canada, a N.A.F.T.A. participating country, or evidence of being entitled to live and work in the United States
  - Complete and submit the Practitioner Profile Questionnaire (11 pages).
  - A criminal background check

P2P exceptions

- TCH should also be aware that Tennessee law provides for a physician-to-physician exception through Tenn. Comp. R. & Reg. R. 0880-2-.16 when:
  - (a) A physician who practices medicine across state lines in an emergency; or
  - (b) A physician who engages in the practice of medicine across state lines that occurs less than once a month or involves fewer than ten patients on an annual basis, or comprises less than one percent (1%) of the physician’s diagnostic or therapeutic practice; or
  - (c) Physicians who engage in the practice of medicine across state lines without compensation or expectation of compensation unless the practice exceeds the limits established by paragraph (6)(b); or
  - (d) The informal practice of medicine in the form of uncompensated consultations regardless of their frequency; or
  - (e) Licensed/registered physicians or surgeons of other states when called in consultation by a Tennessee licensed/registered physician as provided by T.C.A. §63-6-204 (a) (3).

Final Steps

- **Step 4:** TCH receives evidence that an internal review was done determining the distant-site practitioner’s privileges.
- **Step 5:** TCH keeps the distant-site provider updated on any adverse actions, complaints, and performance information about a telemedicine healthcare provider.
- **Step 6:** TCH staff is educated on telemedicine policies and kept updated on changing state and federal legislation.
Case Study - Credentialing Issue

- A hospital relies on the credentialing and privileging decisions of a distant-site telemedicine entity.
- A physician that is providing telemedicine services lied on his background application saying that he had never been convicted of any crime.
- The physician had actually been convicted of two DUIs in the past year.
- The distant-site provider had the physician fill out a background form, but never actually ran the background check.
- While providing telemedicine services, the physician was intoxicated, and prescribed a medication that the patient was allergic to.
- As a result the patient died.
- Who is liable?
- Can a lawsuit be brought in your state for negligent credentialing?

Case Study - Technology Failure

- A physician in a rural part of Nebraska sends a MRI to a distant-site provider located in India so that it can be interpreted overnight.
- Due to an earthquake in India, the power is cut off at the distant-site location and the MRI is never able to be read.
- When the Nebraska physician does their morning rounds they realize the MRI has not been interpreted.
- The physician is unable to reach the distant-site provider due to a total loss of communication services.
- It then takes an additional 6 hours to have the MRI read by another physician.
- During that 6 hour time frame the patient dies due to a condition that, had the MRI been interpreted over night, would have been resolvable.
- Who is liable?

Federal Legislation to Watch

- Bill Number: HR 5475
  - Summary: Requires the Secretary of Health and Human Services (HHS) to encourage and facilitate the adoption of provisions allowing for multistate practitioner practice across State lines for telehealth provided services in the Medicare program. The bill also includes several demonstrations and pilots that would analyze telehealth applications with regard to the bill’s target populations.

- Bill Number: HR 2516
  - Summary: This bill would improve the ability of health care professionals to treat veterans via telemedicine. Specifically, it would allow a VA employed or contracted health care professional to practice at any location in any state regardless of patient or health professional location, if telemedicine is used.

- Bill Number: HR 3081
  - Summary: This bill would amend title XVIII of the Social Security Act to permit certain Medicare providers licensed in a State to provide telemedicine services to certain Medicare beneficiaries in a different State.
Additional Resources

- American Telemedicine Association (ATA)
  - http://www.americantelemed.org

- Center for Connected Health Policy (CCPC)
  - http://cchpca.org

- Center for Telehealth and e-Health Law
  - http://ctel.org/

- American Healthcare Lawyers Association
  - http://www.healthlawyers.org

Questions?

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