Report on
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Weekly News and Compliance Strategies on CMS/OIG Regulations, Enforcement Actions and Audits

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PUBLISHER'S NOTE: **RMC** *will not be published next week. The next issue will be dated August 21.*

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Proposed Physician Regulation Expands Coverage of Telehealth, Drops Modifier

Medicare will soon pay for five more types of telehealth services, according to the proposed 2018 Medicare Physician Fee Schedule Regulation. In addition to the incremental expansion in its coverage of this form of service delivery, CMS floated a proposal to remove a compliance requirement for telehealth, liberating professionals from the GT modifier when they deliver telehealth services at "distant sites," according to the proposed regulation, which was published in the July 21 *Federal Register*.

At the same time, expansion of telehealth coverage got a reality check from the Congressional Budget Office, which just released its scoring of hot new legislation pending in the U.S. Senate. The bill, Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 (S. 870), makes provisions for telemedicine for treating stroke victims but would cost Medicare $180 million more over 10 years, CBO declares. "That's the dilemma for telehealth," says Atlanta attorney Sidney Welch, with Polsinelli. "It increases access, but how do you pay for that access?"

Long term there are savings, but short term it's politically and fiscally difficult to increase telehealth services because of higher initial costs in some cases, Welch says.

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Six Years Later, Hospital Awaits SRDP Outcome; Meanwhile, Stark CAP Is Now Part of Scenery

In 2011, a hospital discovered it was paying surgeons for administrative services under an agreement that had expired a decade earlier. On closer inspection, there was no violation of the Stark self-referral law, but the near miss led the hospital to do a comprehensive review of its physician arrangements.

That was a good move.

The review uncovered a number of physician relationships, including leases and on-call arrangements, that did not fully comport with Stark. "We found a lot of technical violations," the compliance officer tells *RMC*.

The noncompliant contracts represented a tiny fraction of the hospital's physician relationships, which was a good sign about its corporate culture. But millions of dollars were still at risk because all reimbursement flowing from services referred by physicians with noncompliant agreements under Stark has to be returned to Medicare. So the hospital reported the "actual or potential" violations to CMS's Self-Referral Disclosure Protocol (SRDP), to use CMS parlance. Hoping to pay pennies on the dollar, the hospital held its breath.

Almost six years later, the hospital has improved its oversight of physician contracts, and CMS has relaxed some of the regulatory requirements of the Stark Law.

But the hospital is still holding its breath. CMS has yet to offer a settlement under the SRDP.

continued

"We knew we were one of the first to report" after the SRDP was created by the Affordable Care Act, and "we didn't hear anything until 2016," when CMS asked for clarifying documentation. "They wanted to make sure our calculations of the claims that resulted from noncompliant relationships were correct," he says.

But that was it, and time marches on, says the compliance officer, who prefers not to be identified.

Last year CMS relaxed some of the Stark compensation exception requirements, and some of the potential violations the hospital reported may now be compliant.

The Stark Law prohibits Medicare payments to entities for designated health services (DHS), such as inpatient and outpatient services, when patients are referred by physicians who have a financial relationship with the entity, unless an exception applies. To satisfy the exception for office-space leases, the leases must be set out in writing, signed by the parties, last for a year and specify the area they cover. Rent has to be fair-market value, commercially reasonable, and calculated without taking into account the value or volume of the referrals between the parties. The space is used only by the people renting it, who don't pay for more space than necessary to carry out the purpose of renting it, except for common areas. But they should only pay a pro rata share of expenses for common areas. The Stark Law also has an exception for equipment leases that more or less parrots the exception for office space.

Most of the actual or potential violations identified by the hospital centered on "technical issues" around the space the hospital leases to physicians in its cancer center and the equipment leased related to that, the compliance officer says. There wasn't any "glaring issue—we ensured none of the leases took into account the volume or value of referrals." It wasn't about the fair-market value of the leases.

They were block leases, which means a physician rented space to use exclusively on a particular day of the week for certain hours. The rent included the use of common areas, such as waiting rooms and the infusion center. The hospital and physicians signed the leases, but sometimes they weren't signed until the lease was already in effect.

For example, an oncologist had a 36-month lease with the hospital for space in the cancer center for four hours a day, three days a week. It included exclusive use of an office and exam room plus certain common areas, such as a nurse's station. The lease also allowed the oncologist to use one-third of the infusion room when he was at the cancer center, as well as medical and other equipment that was in the cancer center.

M.D.s Used Infusion Rooms at Same Time

One of the potential Stark problems with the space and equipment leases: the oncologist signed it about four months after it took effect. The compliance officer also noted that the lease included equipment (e.g., chemo chairs), but perhaps the description wasn't specific enough.

The lease also allowed the oncologist to share common areas, such as waiting rooms and break rooms, which is fine. But the infusion rooms also were used non-exclusively by the oncologist—in other words, they were used by a number of physicians at the same time—and the hospital allowed for the possibility that it wasn't Stark compliant. CMS has indicated that infusion rooms are more like exam rooms than waiting rooms.

The hospital also transferred ownership of some office equipment to the physician. The equipment was older and had already been paid for, and the hospital didn't want to continue to bear the burdens of repair and maintenance, but this created a compensation arrangement under Stark.

Aside from leases, the hospital had a few on-call arrangements with physicians who cover the emergency room that potentially ran afoul of Stark. For certain days or other short periods of time, the hospital paid physicians to take calls without a written agreement.

And now the hospital waits to hear its fate.

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Washington, D.C., attorney Don Romano, former director of the CMS Division of Technical Payment Policy, says it takes at least three years for CMS to put SRDP cases to bed. "CMS has many more than they can handle," says Romano, with Foley & Lardner LLP. There's a flood of submissions because of the 60-day rule, which requires providers to report overpayments within 60 days of identifying and quantifying them—with the additional threat of reverse False Claims Act lawsuits if they don't comply, he says. "I don't know if there's any end in sight in terms of the backlog," he says. Entering the SRDP essentially suspends the 60-day clock, buying providers more time to get to the bottom of suspected Stark violations, Romano says.

Hospitals always have the option to withdraw their submissions if their technical violations no longer exist in light of changes to the Stark regulations in the 2016 Medicare physician fee schedule regulation *(RMC 2/1/16, p. 1)*.

Hospitals Can Modify Their Disclosures

To give entities that provide DHS more flexibility in the way they establish and document deals with their referring physicians and reduce the flow of submissions to the SRDP, CMS modified the writing requirement under the Stark compensation exception, including employment agreements, leases of office space and equipment, personal services agreements, fair-market-value compensation and isolated transactions. That means DHS entities, such as hospitals, don't necessarily have to cough up a single written contract to satisfy the writing requirement for the compensation exception. There are other ways to prove they have an agreement with physicians, including time sheets, board-meeting minutes and emails. A single piece of documentation won't do the trick unless, of course, it's a contract, CMS said.

And they shouldn't think of it as a before-and-after-2016 decision.

"CMS has said that the idea that you could use several different writings to prove a signature or to prove a written agreement is just a clarification and that it has been its policy," Romano noted. As a result of the 2016 Stark changes, "some people pulled things out of the SRDP and some people have not entered it," Romano says.

If some of a hospital's agreements still have technical violations but some don't, "I believe this would be easily handled by a follow-up letter or email to CMS," he says. "CMS might require a supplemental certification as to the truthfulness and accuracy of the modified disclosure."

In addition to confessing its supposed Stark sins, the hospital's SRDP submission included its corrective action plan, which is entrenched now because so many years have elapsed. For example:

◆ The hospital uses a detailed report for tracking the hours and services performed by medical directors (see box, p. 4). "Before the medical director hours report, it looked like they photocopied from [previous logs]," the compliance officer says. "Some physicians resigned if they were really going to have to be accountable." Meanwhile, the hospital is exploring the use of a smartphone app that would be used by physicians to track their activities and report them to the hospital. It's designed to be more convenient for everyone.

◆ The accounts payable department does not write checks to physicians without confirming the existence of agreements. That's indicated by this notation on checks: "Valid contact on file."

◆ Cancer center leases were redesigned to be fully compliant.

◆ A full-time contract manager, which was a newly created position, oversees all contracts, from purchasing to physician agreements.

◆ New software helps track physician contracts (e.g., when they are due to expire).

◆ The hospital now conducts mandatory training for all hospital managers on physician contracting "and why Stark is important," the compliance officer says.

The Stark saga is not necessarily a grim fairy tale. It set in motion a series of process improvements.

"Finding problems is the sign of a healthy program," he says. "The rules are prone to error so you have to be constantly monitoring."

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Appeals Court OKs FCA Case Without Specific Claims; Relator Lacked Access

A federal appeals court has ruled that a False Claims Act case can move forward even though the whistleblower doesn't mention specific claims. It's good enough under the Federal Rules of Civil Procedure to paint a detailed picture of the alleged fraud, according to the July 27 decision from the U.S. Court of Appeals for the Second Circuit.

The case involves American Medical Response (AMR), the largest ambulance company in the country. Whistleblower Paul Fabula, a former AMR emergency medical technician (EMT), alleged the company submitted Medicare claims for ambulance transports that weren't medically necessary. He was rebuffed by the U.S. District Court for the District of Connecticut because the false claims complaint didn't satisfy Rule 9(b) of the Federal Rules of Civil Procedure, which requires fraud cases

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Documenting the Details of Medical Director Services

Here is one hospital's template for medical directors reporting their services and time every month. The hospital is hoping to make it even more convenient with a smartphone app. Hopefully, the detail will minimize the Stark risk (see story, p. 1), says the compliance officer, who preferred not to be identified.

EXHIBIT C
PHYSICIAN TIME ALLOCATION REPORT

Physician

Date (Month/Year) ____

MEDICAL DIRECTOR/PHYSICIAN'S MONTHLY TIME ALLOCATION REPORT

Personnel and Service Management		
Date(s)	**Activity**	**Time Allocation**
	Professional leadership and management of cardiac surgery team in conjunction with administrator director and/or coordinator.	
	Participation in appropriate management of personnel relative to program development.	
Quality Assurance		
Date(s)	**Activity**	**Time Allocation**
	Utilization review of cardiac surgery services program and services	
	Representation of cardiac surgery in hospital and medical staff P.I activities and committees. (List Committees)	
	Evaluation of safety and appropriateness of services pertaining to patient care.	
	Review of physician competency and credentials for physicians, nurse practitioner, physician assistants and perfusionist.	
	Review and maintains a safe environment for all personnel and patients in the department as mandated by the Joint Commission, OSHA, NLRB, and other regulatory agencies.	
	Review, address and resolve patient care, clinical issues in cardiac surgery and investigate and resolve all patient and staff complaints related to cardiac surgery.	

Documenting the Details of Medical Director Services (continued)

Education (include all programs, for nursing staff and/or physicians)		
Date(s)	**Activity/Program Title**	**Time Allocation**
	Contribute to the development of educational programs including orientation, training, continuing education and performance improvement to maintain a knowledgeable staff.	
	Participation in appropriate orientation/training programs (please list):	
Program Planning and Development		
Date(s)	**Activity**	**Time Allocation**
	Meeting, on a regular basis, with Hospital Nursing Managers and members of the Hospital executive staff responsible for oversight of service	
	Technical advice and assistance related to regulatory applications and permits and any other planning activities affecting service.	
	Policy and procedure development/review	
	Review/evaluate equipment or supplies	
Financial and Data Management		
Date(s)	**Activity**	**Time Allocation**
	Preparation of Capital Budget for Dialysis Services, including both review and expenditures	
Additional Services Provided (explain in detail)		
Date(s)	**Activity**	**Time Allocation**
		TOTAL HOURS

Physician Signature **Date** **Department Director/VP** **Date**

to be pled with "particularity." Fabula's complaint, the district court ruled, was a nonstarter "because it provides neither details, such as invoice numbers, invoice dates, and amounts billed or reimbursed, regarding actual requests for payment made to the government, nor a factual basis for its allegations that AMR submitted false claims."

But the appeals court disagreed, and Fabula's lawsuit will go on to live another day. It was remanded to the district court.

Whistleblowers Also Must Say Why

Minneapolis attorney Kevin Riach says the message is if a complaint has enough details about the purported fraud to corroborate the allegation that false claims were submitted, it's enough to survive Rule 9(b). "An interesting wrinkle is the appeals court indicated that you have to specifically plead why you are not able to identify specific claims or invoices," says Riach, with Fredrikson & Byron.

According to the decision, Fabula, who worked for AMR in its New Haven branch between August 2010 and December 2011, alleged that AMR required EMTs and paramedics to "revise or recreate" documentation to support the medical necessity of ambulance trips to ensure Medicare reimbursement, according to a description of the complaints in the court decision.

When AMR does an ambulance run, EMTs are required to fill out a patient care report (PCR), which contains details about the patient—name, date, time and address of the pick-up, and the name of the medical facility the patient is being delivered to—and submit it electronically. The content determines whether the ambulance trip is medically necessary. "Supervisors at AMR specifically instructed EMTs and paramedics how to modify the PCRs by including false or misleading information, and admitted to Fabula that the purpose of such revisions was to qualify the run for Medicare reimbursement," the court decision stated. For example, calm dementia patients were routinely described as having a violent history.

Fabula said in the complaint he refused to falsify the documentation.

As the appeals court delved into the details, it explained that Rule 9(b) "ordinarily requires a complaint alleging fraud to '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" But "the adequacy of particularized allegations under Rule 9(b) is…case- and context-specific."

Because AMR's EMTs were confined to the garage, Fabula couldn't provide certain billing information to support the false claims allegations, the appeals court noted. Yet his complaint has conceivable allegations that the bills submitted to the government were under AMR's control and were actually submitted, according to the appeals court.

And there are loads of other details about the alleged scheme: how it worked, when it transpired, why and the kinds of patients at the heart of it, the appeals court said. "These allegations are not merely general or conclusory," the appeals court stated. It also refused to require every whistleblower to personally have proof that false invoices were sent to the government. "A complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge," the appeals court asserted. However, the appeals court cautioned, that's not a "license" for bad-faith allegations.

Other appeals courts have ruled in a similar way in false claims cases, Riach says. "The trend line is such that all circuits probably will land in the same spot," he notes. If the fraud scheme is plausible, whistleblowers have a shot even if they can't cite a specific false claim. But false claims lawsuits are doomed when they're filed as a fishing expedition, "in the hopes of discovering something had happened," Riach said.

Contact Riach at kriach@fredlaw.com. ✧

CMS Expands Telehealth Coverage

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It's one reason why in 2018, CMS is again adding reimbursement for telehealth services "bit by bit," Welch says. "It's consistent with what we have seen happening year after year," she says. "CMS is not opening the floodgates on telehealth services. That ties in with the overall threshold questions of telehealth services historically. Can telehealth services provide the same level of quality as laying hands on?" But they're a freight train that can't be stopped—"it keeps popping up in legislation and agency rules," and commercial payers, consumers and progressive payment models, such as accountable care organizations, are pushing it along, even if CMS moves at a "cautious pace," Welch says. Whether telemedicine moves fast or slow, providers have to be mindful of the compliance issues, which include fraud and abuse, HIPAA and licensure.

At the moment, Medicare covers 37 services delivered by telehealth in rural areas, which includes counties outside of Metropolitan Statistical Areas (MSAs) or in health-professional shortage areas either outside of an MSA

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or in a rural census tract. Telehealth services have to be furnished in an "originating site," such as hospitals, physician practices and other approved locations. Providers must use face-to-face, interactive audio and video telecommunications systems that enable real-time communication between the distant-site provider and the patient at the originating site. When providers deliver telehealth services, they must append the GT modifier to CPT codes. Otherwise, there's no way for Medicare administrative contractors (MACs) to distinguish between conventional and telehealth services. Without the GT modifier, claims are denied *(RMC 6/20/16, p. 3)*.

New Modifier Made Old One Moot

Also, in 2017, CMS added another telehealth modifier. Distant sites—where the professional services occur—now have to put a place-of-service code, POS 02, on their claims when telehealth services are delivered in their facility *(RMC 11/14/16, p. 6)*. CMS uses it to adjust relative value units (RVUs) to the facility practice expense for the service. Before Jan. 1, 2017, providers reported the POS code for the location where the patient was seen (also known as the originating site) as if the service was delivered in person. That muddied the waters of reporting telehealth places of service. POS 02 solved the problem. Distant site providers that report the new POS code receive the facility physician expenses RVU, which is lower than the practice physician expenses RVU.

Now that POS 02 exists, CMS is proposing to ditch the GT modifier on professional claims for distant site practitioners, according to the fee schedule regulation.

In other words, the proposed change recognizes that the GT modifier becomes redundant for clinicians, Welch says. "If you have appropriate reporting of the POS that certifies you meet requirements of telehealth services, you don't need the distant-site modifier on the claim," she says. "It's an administrative burden they are relieving."

Hospitals don't use the POS code in this context, so they will continue to be required to use the GT modifier on institutional claims, CMS explains.

As for the careful expansion of Medicare coverage of telehealth, CMS says in the proposed rule that it selects services that either (1) are similar to services on the covered telehealth list, which may include the way patients interact with providers and the use of interactive audio and video equipment, or (2) are not similar to covered telehealth services but offer evidence that "the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient."

For 2018, CMS determined that coverage should include:

◆ HCPCS code G0296 (visit to determine low-dose computed tomography (LDCT) eligibility);

◆ CPT code 90785 (Interactive Complexity);

◆ CPT codes 96160 and 96161 (Health Risk Assessment);

◆ HCPCS code G0506 (Care Planning for Chronic Care Management); and

◆ CPT codes 90839 and 90840 (Psychotherapy for Crisis).

CMS's increase in coverage of telehealth/telemedicine services over time is obvious from the screen-to-screen services in hospitals, Welch notes. "It's common for subspecialists to rotate through smaller clinics. Dermatologists are way out in front. They take pictures and decide whether the person needs to go to the office or can get medical advice remotely," she says. "It's the uberization of health care."

Of course, telemedicine is vulnerable to abuse or allegations of abuse. Last year, prosecutors settled the first False Claims Act lawsuit in a telehealth case. Connecticut psychiatrist Anton Fry and his Danbury-based mental health practice, CPC Associates, Inc., agreed to pay $36,704 to resolve allegations that they billed Medicare for services provided over the phone from Jan. 1, 2008, to June 1, 2015 *(RMC 8/1/16, p. 1)*. Fry allegedly didn't meet the patients or treat them in person, and the services didn't qualify as telehealth.

While CMS moves cautiously with telemedicine, the rest of the industry, partly sparked by consumer demand, rushes full speed ahead with commercial and, in some

CMS Transmittals and *Federal Register* Regulations

July 28 - Aug. 3

Live links to the following documents are included on *RMC*'s subscriber-only webpage at www.hcca-info.org. Please click on "CMS Transmittals and Regulations."

Transmittals

(R) indicates a replacement transmittal.

Pub. 100-04, Medicare Claims Processing Manual

- July Quarterly Update for 2017 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule, Trans. 3824 (Aug. 2, 2017)
- National Coverage Determination (NCD20.8.4): Leadless Pacemakers, Trans. 3815 (July 28, 2017)

Pub. 100-03, Medicare National Coverage Determinations

- National Coverage Determination (NCD20.8.4): Leadless Pacemakers, Trans. 201 (July 28, 2017)

Federal Register

Final Regulations

- Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2018, 82 Fed. Reg. 36238 (Aug. 3, 2014)

contexts, government payers. Providers, however, have to carefully weigh licensure, privacy, and fraud and abuse issues, which at times have slowed down its use, attorneys say. Telemedicine is being embraced partly because of the demand for innovative technology and the need for a solution to shortages of certain provider types, says Washington, D.C., attorney Lidia Niecko-Najjum, with Polsinelli.

But there are regulatory barriers. "Health care is not a normal business because of regulatory bodies," she notes. "We really have regulatory limits, and reimbursement is a huge one. We have been constrained in what we have seen on the telehealth front."

Teladoc Case Was a Cliffhanger

Licensure is another regulatory stumbling block, but things are moving along faster there, she says. Eight states offer special telemedicine licenses, and last year, 44 states introduced 150 telehealth-related laws. Some are very flexible and some restrictive, and they govern a range of activities, from prescribing to the physician-patient relationship, Niecko-Najjum says. "You have inconsistency on state licensure." Hopefully it will be alleviated with the Interstate Medical Licensure Compact introduced in 2015 by the Federation of State Medical Boards. Practitioners would keep their licensing and disciplinary authority, but they would share information and processes necessary to license and regulate physicians who practice telemedicine across state lines, Niecko-Najjum says.

Not all the oversight comes from the legislature, and sometimes this complicates the progress of telemedicine, she says. In April 2015, the Texas Medical Board approved a rule that banned physicians from prescribing medications until they established a physician-patient relationship, which meant diagnosing the patient in an examination performed during a face-to-face encounter, Niecko-Najjum says. The rule was seen as a challenge to Dallas-based Teladoc, the largest telehealth company in the country, which then sued the Texas Medical Board on antitrust grounds.

The practice of telemedicine won this round. In October 2016, the Texas Medical Board abandoned its appeal, and the case was sent back to federal district court, where both sides agreed to a stay. The conflict may soon be moot. In March, the state Senate passed a telehealth bill (S.B. 1107) that drops the face-to-face requirement as long as physicians abide by the standard of care and don't prescribe drugs that induce abortions, and now the bill is pending in the House.

"This is a great example of how we are seeing the shift/trend to embrace telehealth at the state level," Welch notes.

Another stumbling block for telemedicine is HIPAA privacy and security compliance. HIPAA applies to telemedicine encounters, but sometimes it's hard for providers to get their arms around them depending on the medium—video, audio and images—and vendors play a big part, Welch says. "Where do the medical records go—the distant or originating site? Who is responsible for maintaining the medical records?" If there's a vendor, is it safeguarding those things? How do you know? A number of vendors advertise themselves as HIPAA compliant, but they may or may not be. "Make sure the telemedicine function won't get stuck with all the risks," she says. The buck stops with the providers; they can't rely on vendors to accomplish HIPAA compliance, although they are expected to verify that vendor technology is capable of HIPAA compliance.

Bottom line: "You won't avoid HIPAA with telehealth."

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NEWS BRIEFS

◆ **Kim Brandt, chief oversight counsel for the Senate Finance Committee, is leaving after six years to take a top job at CMS.** Brandt will be Principal Deputy Administrator for Operations at CMS, where she previously worked as head of Medicare program integrity when CMS was ramping up its oversight.

◆ **Attorney General Jeff Sessions on Aug. 2 announced the formation of an Opioid Fraud and Abuse Detection Unit, which will use data analytics to combat opioid-related health care fraud.** DOJ will identify and prosecute people who contribute to the opioid epidemic. There also will be a three-year pilot to fund 12 assistant U.S. attorneys who will focus exclusively on investigating and prosecuting health fraud stemming from opioid abuse. Providers have been on guard about their prescriptions of high-dose opioids because of Sessions' concerns and are encouraged to reinforce their documentation *(RMC 7/31/17, p. 1)*. Visit http://tinyurl.com/y7c7w2nc.

◆ **CMS on Aug. 2 finalized the inpatient prospective payment system (IPPS) regulation, which takes effect Oct. 1.** Visit http://tinyurl.com/y7aq4k5n.

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