

Proceed With Caution: Matters to Consider for Business Lawyers Transitioning Into Health Care

By Craig B. Garner

Introduction

While the subject of health care law makes headlines daily across the nation, there is still a sizeable chasm between health care lawyers and their business counterparts. Sometimes complicated, health care law is by no means exclusive, and opportunities abound for an able practitioner. Notwithstanding this, in today's climate of reform it is essential that those practicing American health care law honor and obey the hierarchy surrounding its discipline as it struggles to stay afloat amid a rising tide of constitutional, partisan and fiscal challenges.

In most states, attorneys are mindful that when venturing into areas of law outside their usual practice, rules of professional conduct apply. A District Court in the District of Columbia recently repeated a familiar quote that health care law, and the Medicare statutes in particular, are "among the most completely impenetrable texts within human experience." Complications notwithstanding, there is a pressing need to advance this body of authority, not to mention the nation's health care system, beyond its fledgling form (commonly referred to as the Affordable Care Act). What began as a mere 2,700 pages of codified reform may eventually be tens of thousands. This will require active participation from attorneys representing practically all areas of law, although when it comes to matters of health care law, it is always best to proceed with caution.

When venturing into areas of law outside their usual practice, attorneys should be mindful of the state-specific standards to which they are held. Rule 3-110 of the California Rules of Professional Conduct sets the standard on the west coast, just as Rule 1.1 of the New York Rules of Professional Conduct applies on the east. Absent the requisite skill to accommodate a client's needs, an attorney may still engage and adhere to the statutory definition of competence by "associating with or, where appropriate, professionally consulting another lawyer reasonably believed to be competent" or "by acquiring sufficient learning and skill before performance is required."¹ In 2003, a California Appellate Court explained: "attorneys are expected 'to possess knowledge of those plain and elementary principles of law which are commonly known by well informed attorneys, and to discover those additional rules of law which, although not commonly known, may readily be found by standard research techniques.'"²

However, due to the sheer volume and complexity of information generated regularly in the wake of reform, modern health care law exists in a league of its own. To be sure, there is nothing otherworldly about health care

law,³ and a conscientious advocate can find the answers he seeks given enough time and resources. Yet even the savviest business lawyer should be mindful before accepting a new assignment involving health care concerns, as the fiduciary pathway can be treacherous and unforgiving. The ever-evolving body of laws governing today's health care industry bears at least partial blame for the inherent disconnect between traditional notions of business (referenced occasionally in a state's Corporations,⁴ Corporations and Associations⁵ or General Business Code,⁶ for example) and the business of health care (found within a plethora of statutory domiciles in various states, including California,⁷ New York⁸ and Texas,⁹ among others).¹⁰ Regardless of where it is encountered, health care law should never be underestimated, even if its underlying logic exists outside the scope of case law and statutes frequented by a business lawyer on any given day.

The False Claims Act, 150 Years in the Making

To further confuse the issue, many of the core tenets central to health care law are inherently inconsistent with those meanings employed on a regular basis by the corporate attorney, such as "goods and services," "financial interests," "referrals," "discounts" and "rebates." The situation has not improved with the passage of the Patient Protection and Affordable Care Act,¹¹ as amended by the Health Care and Education Reconciliation Act¹² (collectively referred to as the Affordable Care Act or health care reform) particularly in regard to matters of health care fraud and abuse. Dating back to the American Civil War, the False Claims Act (FCA) has over time become both the federal and state governments' "primary litigative tool for combating fraud."¹³ At its core, the FCA imposes liability on anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval."¹⁴

What began as a way to protect the Union Army from purchasing substandard horses, faulty weaponry, and inedible provisions has evolved considerably since Congress passed the FCA in 1863.¹⁵ In its present incarnation under the Affordable Care Act, a health care provider must return any "overpayment" of federal funds within sixty days after identifying the error or risk liability under the FCA.¹⁶ However, the meaning of the term "overpayment" extends beyond a simple miscalculation of price in response to which a refund or store credit will suffice.

Under federal law, overpayments can result from unintentional billing errors, overutilization or by working

with an excluded vendor. They can also occur when a facility does not employ accurate procedures for billing and collecting in connection with hard work on behalf of real patients, unnecessary work with not-so-real patients, and necessary work for patients within 72 hours of a hospital inpatient admission or discharge.¹⁷ An overpayment may include a duplicate payment to a hospital by a patient and her automobile insurer.¹⁸

It may also apply in “the situation where a provider is given money by Medicare to pay for certain health care services, and the provider contracts with a third party who, in turn, provides those services, but the provider fails to liquidate the liability by paying the third party within a designated period of time.”¹⁹ There may exist both “anticipated” overpayments as well as “erroneous” overpayments,²⁰ and a delay of as much as fourteen years in attempting to recover an overpayment should be considered reasonable.²¹

Exclusion From the Medicare Program

Yet another concept that has grown far more expansive under the Affordable Care Act is the notion of what it means to be “excluded” from participation in a health care program funded at least in part by the Federal government, and the potential ramifications of such exclusion from a business standpoint.²² As a general rule, the Federal government requires advanced approval of every entity that participates in the delivery of health care under a federal program such as Medicare. In the event that any one participant in a provider’s delivery of health care is either unauthorized or excluded²³ from participation by the Federal government, everything related to the actual remuneration of these health care services by the Federal government may constitute an overpayment and/or false claim.²⁴ In essence, any items or services furnished by an excluded individual or entity are not reimbursable by any Federal health care program, including monies paid to another, third party provider or supplier that is an authorized participant, such as a doctor or hospital. This creates an implied indemnification of any health care provider who receives Federal funds in exchange for the delivery of medical services, yet fails to afford that same provider any viable remedy against a third party who bears technical culpability for the break in the chain, thereby rendering the entire reimbursement *void ab initio*. A single weak link effectively nullifies the entire chain.

No matter where on the vertical ladder of delivery an excluded provider may stand, reimbursement is not permissible for anyone, and violations may result in potential criminal penalties.²⁵ This includes those administrative and management services that are not directly related to health care but are nonetheless a necessary component in the ultimate delivery of health care services. Services performed by excluded parties such as nurses, pharmacists, ambulance drivers, social workers, claims processors, or even the person who sells, delivers and/or refills

an order for a medical device are thereby prohibited.²⁶ Failure to follow these rules closely exposes a health care provider to potential civil money penalties of \$10,000 for each item or service that bears some nexus to an excluded individual, treble damages for the amount of each specific claim, and possible exclusion for the health care provider himself or herself, who may have been unaware of the circumstances rendering his or her treatment problematic in the eyes of the government.²⁷

It should thus come as no surprise that under the Affordable Care Act, participation in the Medicare program may require a heightened level of advanced screening, such as criminal background checks, fingerprinting, licensure verification and unannounced visits.²⁸ As of March 25, 2012, these procedures will apply to nearly everyone involved in the delivery of care under the Medicare program, either directly or indirectly.²⁹ While this may on the surface appear to be somewhat disruptive, its intent is to protect providers from unwittingly collaborating with excluded parties who may cause them not only to forfeit their right to reimbursement, but also incur substantial penalties. Although typically associated with criminal law cases, the legal metaphor “fruit of the poisonous tree”³⁰ provides an excellent analogy for the ways in which the slightest oversight can lead to substantial financial penalties.

The Fraud and Abuse Labyrinth

In an attempt to curtail the ever-present specter of medical fraud, both state and federal governments have created a series of provisions designed to police providers and highlight areas where conflicts of interest may arise. Fraught with complexity and comprised of volumes upon volumes of information in the form of statutory authority, case law decisions, and secondary references, Stark laws, Anti-Kickback statutes and laws governing outpatient referral³¹ give the Commerce Clause³² a run for its money in terms of complexity. And yet, it is not the nature of the laws that is problematic from the viewpoint of a business lawyer, but rather the 28 pages of double-columned regulatory exceptions (also known as “Safe Harbors”)³³ to the criminal penalties for acts involving federal health care programs.³⁴ When used accordingly, these statutory exceptions can potentially insulate a health care provider from liability under the Stark and Anti-Kickback laws, not to mention the few hundred advisory opinions generated by the Office of the Inspector General.³⁵

Some of the more common Safe Harbor provisions include investment interests, office space and equipment rental, personal services and management contracts, the sale of a practice, referral services, discounts, employees, group purchasing organizations, waiver of beneficiary coinsurance and deductible amounts, physician recruitment, investments in group practices, ambulatory surgical centers, ambulance replenishing, and electronic health records.³⁶ Outside of the health care context, many such

transactions are considered ordinary at best, and there are without question other specialty areas among business lawyers that also include higher standards of care. However, with health care expenditures (NHE) accounting for almost 18% of the nation's gross domestic product, amounting to approximately \$2.5 trillion as of 2009,³⁷ it is not entirely unexpected that health care law is trying to keep pace, and the physical and mental demands such labyrinthine legislation may impose upon the unwary business lawyer should never be underestimated. With such an expansive regulatory reach and potential liability emanating from so many possible points of origin, extreme vigilance and an ever-present eye to copious, sometimes seemingly unreasonable or unfair, details must serve as the foundation for any health care law practice.

Health Care's Version of the Recall

It is not uncommon for federal or state laws to mandate that businesses notify their customers in certain events, such as during product safety recalls in automobiles, potential health threats relating to food products, and substantive or technical concerns in the pharmaceutical industry. Due to concerns over patient privacy, the health care industry must take the idea of patient notification to a whole new level. Under the Health Information Technology for Clinical and Economic Health (HITECH) Act,³⁸ any "covered" entity that maintains "unsecured" protected health information (PHI) and "discovers" a "breach of such information" must notify each individual whose PHI "has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach."³⁹ This rule also applies to business associates working with an entity for which disclosure is required under the HITECH Act.⁴⁰

The regulations provide for the method of notification (mail, email, or telephone, in certain instances),⁴¹ establish protocol should the issue involve more than ten individuals, and set forth further requirements for issues involving more than 500 individuals.⁴² Federal regulations also specify what the notice must include for each type of infraction.⁴³ Finally, there is often a fine when a breach is proven, and neither HITECH nor HIPAA (Health Insurance Portability and Accountability Act of 1996)⁴⁴ offers exceptions. With civil penalties ranging from \$100 to \$50,000 for each HIPAA or HITECH-related violation, cumulative penalties can amount to as much as \$1,500,000 in any calendar year.⁴⁵ Where there is an "intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, the penalty may not exceed \$250,000, imprisonment up to 10 years, or both."⁴⁶

We Cannot Refuse the Right to Serve

In an effort to counteract "patient dumping," wherein hospitals refuse to treat people due to lack of insurance or inability to pay, Congress passed the Emergency Medical

Treatment and Active Labor Act (EMTALA) in 1986.⁴⁷ EMTALA requires every hospital that receives federal funding to treat any patient with an emergency condition in such a way that, upon the patient's release, no further deterioration of the condition is likely. No hospital may release a patient with an emergency medical condition without first determining that the patient has been stabilized, even if the hospital properly admitted the patient. Under EMTALA, patients requesting emergency treatment can only be discharged under their own informed consent or when their condition requires the services of another hospital better equipped to treat the patient's concerns.⁴⁸

There has been an abundance of debate regarding the propriety of these requirements, specifically regarding their impact on the emergency health care system in the United States.⁴⁹ Simply put, the idea behind EMTALA places a considerable burden on participating emergency departments by allowing a buyer of certain goods (*i.e.*, the patient) to obtain certain goods (*i.e.*, medical care) from a seller of certain goods (*i.e.*, the hospital), though the seller must still perform his or her duties regardless of whether the buyer is able to pay, and there exists no viable remedy to prevent such a scenario from happening repeatedly. While other industries have specific remedies for addressing such issues,⁵⁰ these methods rarely apply in the health care sector.⁵¹ Even provisions to protect business transactions upon seller's discovery of buyer insolvency do not translate well in the realm of health care law,⁵² placing providers in the unenviable position of having to provide their services atop a business model too weak to allow for continued sustainability.

Health care law is by no means exclusive, and opportunities abound for an able practitioner hoping to transition at any stage of his or her career. In today's climate of reform, it is essential that those practicing American health care law honor and obey the hierarchy surrounding its discipline as it struggles to stay afloat amid a rising tide of constitutional challenges. It comes as no surprise that even after the Supreme Court's landmark decision in June confirming the constitutionality of the Affordable Care Act,⁵³ health care law continues its reign in the spotlight. Even though Chief Justice Roberts set the stage for the November elections while casting uncertainty for the future of the Affordable Care Act,⁵⁴ health care lawyers are sure to remain standing.

Endnotes

1. Cal. Rules of Prof'l Conduct R. 3-110(C) (1992); *see also* Ala. Rules of Prof'l Conduct R. 1.1 (2012); Colo. Rules of Prof'l Conduct R. 1.1 (2008); N.Y. Rules of Prof'l Conduct R. 1.1(b) (2009); Tex. Disciplinary Rules of Prof'l Conduct R. 1.01 (2005).
2. *Camarillo v. Vaage*, 130 Cal. Rptr. 2d 26, 32 (Cal. Ct. App. 2003) (quoting *Smith v. Lewis*, 530 P.2d 589, 595 (Cal. 1975)); *see also* *McIntyre v. Comm'n for Lawyer Discipline*, 169 S.W.3d 803, 807-08 (Tex. App. 2005); *In re Jayson*, 832 N.Y.S.2d 696, 698 (App. Div. 2007); *Davis v. Alabama State Bar*, 676 So.2d 306, 310 (Ala. 1996);

- Disciplinary Counsel v. Hoppel, 2011-Ohio-2672, 129 Ohio St. 3d 53, 54, 950 N.E.2d 171, 173.
3. *But see* Catholic Health Initiatives—Iowa v. Sebelius, 841 F. Supp. 2d 270, 271 (D.D.C. 2012) (“Picture a law written by James Joyce and edited by E.E. Cummings [sic]. Such is the Medicare statute, which has been described as ‘among the most completely impenetrable texts within human experience.’”) (quoting Rehab. Ass’n of Va., Inc. v. Kozlowski, 42 F.3d 1444, 1450 (4th Cir. 1994)). The District Judge also noted that “[t]he Court clarifies, however, that by making this analogy, it is referring not to Joyce’s early work, such as *Dubliners* or *A Portrait of the Artist as a Young Man*, but his later period, specifically *Finnegan’s Wake*.” *Catholic Health*, 841 F. Supp. 2d at 271 n.1.
 4. *See, e.g.*, Cal. Corp. Code.
 5. *See, e.g.*, Md. Code Ann., Corps. & Ass’ns Code.
 6. *See, e.g.*, N.Y. Gen. Bus. Law.
 7. *See e.g.*, Cal. Health & Safety Code, Cal. Welf. & Inst. Code, Cal Ins. Code, Cal. Lab. Code, and Cal Gov’t Code, among others.
 8. *See, e.g.*, N.Y. Ins. Law, N.Y. Pub. Health Law, N.Y. Mental Hyg. Law, N.Y. Retire. & Soc. Sec. Law, N.Y. Vol. Ambul. Workers’ Ben. Law and N.Y. Workers’ Comp. Law, among others.
 9. *See, e.g.*, Tex. Health & Safety Code Ann. and Tex Loc. Gov’t Code Ann., among others.
 10. *See also* 42 U.S.C. (2012) (Public Health and Welfare); 25 U.S.C. §§ 1601–83 (2012) (Indian Health Care); 31 U.S.C. (2012) (Money and Finance); 38 U.S.C. §§ 7301–68 (2012) (Veterans Health Administration). In addition to these state and federal statutes, there exists an equally expansive body of state and federal regulatory authority. *See, e.g.*, 8 U.S.C. (2012) (Industrial Relations); 17 U.S.C. (2012) (Public Health); 28 U.S.C. (2012) (Managed Health Care); *see also* 25 C.F.R. (2012) (Indians), 38 C.F.R. (2012) (Pensions, Bonuses, and Veterans’ Relief), 42 C.F.R. (2012) (Public Health).
 11. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).
 12. Healthcare and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (2010).
 13. *United States ex. rel. v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993) (quoting Senate Judiciary Committee, False Claims Amendments Act of 1986, S. Rep. No. 345, 99th Cong., 2d Sess. 2 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266).
 14. 31 U.S.C. § 3729(a)(1)(A) (2012).
 15. *See* 12 Stat. 696 (Mar. 2, 1863).
 16. *See* 42 U.S.C. § 1320a-7k (2012); *see also* 18 U.S.C. § 1035 (2012) (false statements relating to health care matters); 18 U.S.C. § 1001 (2012) (false statements as to matters under federal jurisdiction); 31 U.S.C. § 3729(a)(1) (the Fraud Enforcement and Recovery Act). *Cf.* Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (Feb. 16, 2012) (to be codified at 42 C.F.R. pts. 401 and 405) (clarifying the requirements for providers and suppliers receiving funds under the Medicare program to report and return overpayments).
 17. *See generally* 42 U.S.C. § 1320a-7b (2012) (outlining criminal penalties for acts relating to federal health care programs).
 18. *Buckner v. Heckler*, 804 F.2d 258, 259–60 (4th Cir. 1997).
 19. *See In re Slater Health Center*, 398 F.3d 98, 100 (1st Cir. 2005).
 20. *Carleson v. Unemployment Ins. Appeals Bd.*, 64 Cal. App. 3d 145, 153 (Cal. Ct. App. 1976); *see also* *Holy Cross Hosp. of Silver Spring, Inc. v. Maryland Employment Sec. Admin.*, 421 A.2d 944, 946 (Md. 1980).
 21. *See generally* *Robert F. Kennedy Med. Ctr. v. Department of Health Svcs.*, 61 Cal. App. 4th 1357 (Cal. Ct. App. 1998).
 22. This includes Medicare and Medicaid.
 23. The Federal government, and specifically the Office of the Inspector General, is required by law to exclude from participation in all Federal health care programs individuals or entities convicted of certain offenses, such as Medicare or Medicaid fraud, patient abuse or neglect, or felony convictions for other health care related fraud or misconduct. *See, e.g.*, 42 U.S.C. § 1320A-7(a) (2012). The OIG also has discretion to exclude from participation in all Federal health care programs individuals or entities with misdemeanor convictions related to health care fraud, fraud in a non-health care program that is funded by a federal, state or local government agency, or for providing unnecessary or substandard service. *See, e.g.*, 42 U.S.C. § 1320A-7(b) (2012).
 24. *See, e.g.*, 42 C.F.R. § 1001.1901 (2012).
 25. 42 U.S.C. § 1320a-7b (2012).
 26. *See, e.g.*, 42 U.S.C. § 1395x(b) (2012) (defining inpatient hospital services).
 27. *See, e.g.*, 42 U.S.C. § 1320a-7a (2012); 42 C.F.R. § 1001.3002 (2012).
 28. 42 U.S.C. § 1866j(2) (2012).
 29. Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5862, 5865 (Feb. 2, 2011).
 30. *See Nardone v. United States*, 308 U.S. 338, 341 (1939) (first use of the phrase “fruit of the poisonous tree”); *Silverthorne Lumber Co. v. United States*, 251 U.S. 385 (1920) (first articulation of the concept behind the phrase).
 31. *Stark* (the Medicare self-referral prohibitions, codified at 42 U.S.C. § 1395nn (2012)), *AKS* (the Federal Anti-Kickback statutes, 42 U.S.C. § 1320a-7b(b) (2012), and *PORA* (California’s Physician Outpatient Referral Act, CAL. BUS. & PROFS CODE § 650, *et seq.*).
 32. U.S. CONST. art. I, § 8, cl. 3 (“To regulate commerce with foreign nations, and among the several states, and with the Indian tribes.”).
 33. *See* 42 C.F.R. § 1001.952 (2012).
 34. *See, e.g.*, 42 U.S.C. § 1320a-7b (2012).
 35. The OIG issues advisory opinions about the application of its fraud and abuse authorities to the requesting party’s existing or proposed business arrangement. 42 U.S.C. § 1320a-7d(b) (2012); 42 C.F.R. § 1008 (2012).
 36. *See* 42 C.F.R. § 1001.952 (2012).
 37. United States Department of Commerce, Bureau of Economic Analysis; Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group. The NHE calculates total annual spending for health care in the United States (goods and services), in addition to total administrative spending each year, as well as the net cost of private health insurance, among other things. *See* Micah Hartman et al., *Health Spending Growth at a Historic Low in 2008*, 29 HEALTH AFF. 147 (Jan. 2010) (citing Centers for Medicare & Medicaid Services, national health expenditure accounts: definitions, sources, and methods used in the NHEA 2008).
 38. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, Feb. 17, 2009, 123 Stat 115.
 39. 42 U.S.C. § 17932.
 40. 42 U.S.C. § 17931(a).
 41. 42 U.S.C. § 17932(e).
 42. 42 U.S.C. §§ 17932(e)(3), (e)(4).
 43. 42 U.S.C. § 17932(b), (f).
 44. Health Insurance Portability and Accountability Act, Pub. L. No. 104–191, Aug. 21, 1996, 110 Stat 1936.
 45. 42 U.S.C. § 1320d-5(a)(3).
 46. 42 U.S.C. § 1320d-6(b)(3).

47. An Act to provide for reconciliation pursuant to section 2 of the first concurrent resolution on the budget for fiscal year 1986 (S. Con. Res. 32, Ninety-ninth Congress), Pub. L. No. 99-272, Apr. 7, 1986, 100 Stat 82.
48. 42 U.S.C. § 1395dd (2012). Notwithstanding the requirements of EMTALA, including an undisputed obligation to treat undocumented or illegal aliens, the Affordable Care Act does not provide for any mechanism to insure this same category of individuals.
49. See, e.g., Renee Y. Hsia, M.D., *Factors Associated with Closures at Emergency Departments in the United States*, 305 (19) JAMA 1978 (May 18, 2011); S. Trzeciak and E.P. Rivers, *Emergency Department Overcrowding in the United States*, 20 EMERG. MED. J. 402-05 (2003).
50. See, e.g., CAL. PENAL CODE § 487 (grand theft larceny); MINN. STAT. § 609.52 (theft); FLA. STAT. § 812.012 (theft, robbery and related crimes); U.S. CONST. amend. V (Takings Clause).
51. A recent California Supreme Court decision held that emergency department physicians who do not contract with a health maintenance organization (HMO) may not bill the HMO's members for any amounts that remain unpaid by the HMO, an industry practice commonly known as "balance billing." *Prospect Med. Grp. v. Northridge Emerg. Med. Grp.*, 198 P.3d 86 (Cal. 2009); *but see* CAL. PENAL CODE § 484b ("Any person who receives money for the purpose of obtaining or paying for services, labor, materials or equipment and willfully fails to apply such money for such purpose...and wrongfully diverts the funds to a use other than that for which the funds were received, shall be guilty of a public offense....").
52. Compare CAL. COM. CODE § 2702 and IND. CODE § 26-1-2-702 ("Where the seller discovers the buyer to be insolvent he may refuse delivery except for cash including payment for all goods theretofore delivered under the contract, and stop delivery....") with Christopher Palmeri, *California Faces Cash Shortfall by March on Low Receipts, Controller Says*, BLOOMBERG, Jan. 31, 2012, <http://www.bloomberg.com/news/2012-01-31/california-faces-cash-crisis-by-march-controller-chiang-says.html> ("Unlike 2009, when [Controller John Chiang] was forced to issue IOUs to creditors, the controller said the current cash shortfall can be managed through payment delays, as well as external and internal borrowing.").
53. Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).
54. Although the Affordable Care Act survived the Supreme Court, whether or not it will escape partisan politics unscathed remains to be seen. In his conclusion, Chief Justice Roberts aptly set the stage for what is to come in November: "the Court does not express any opinion on the wisdom of the ACA. Under the Constitution, that judgment is reserved to the people." *Id.* at 2608.

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