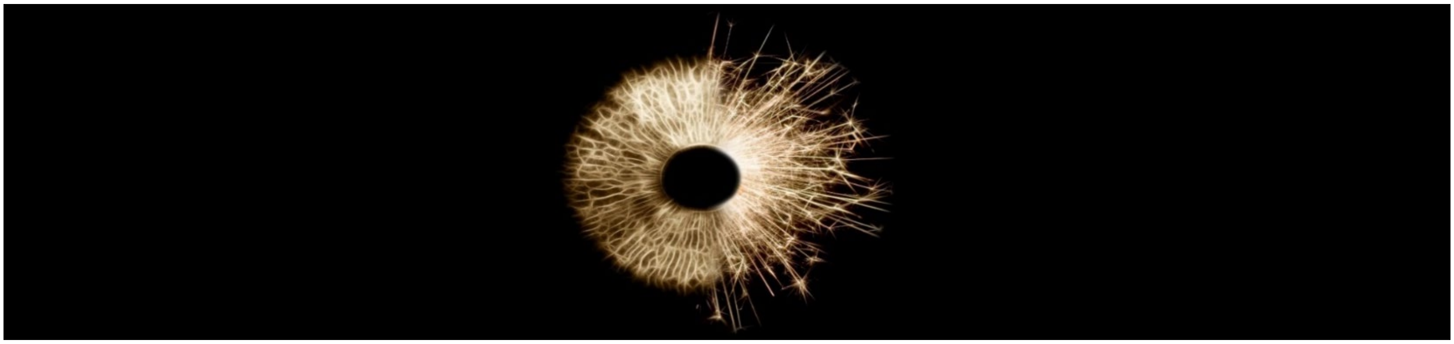


HIPAA compliance in the AWS cloud

Introduction

What is HIPAA?

The Health Insurance Portability and Accountability Act (HIPAA) was introduced in 1996. Title II of the regulation, known as the Administrative Simplification (AS) provisions, consists of the Privacy Rule and the Security Rule. Within the HIPAA Privacy Rule, national standards were established to protect individuals' medical records and other personal health information. The Security Rule requires appropriate administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information (ePHI). The HIPAA rules apply to covered entities such as health plans, health care clearinghouses, health care providers that conduct certain health care transactions electronically, and business associates of covered entities.

To date, the OCR has settled non-compliance cases, resulting in fines of more than 78 million dollars

Based on enforcement highlights published by the OCR as of May 3, 2018

Why HIPAA matters

HIPAA was designed to protect patient data and a growing number of health care data breaches have led to increased HIPAA enforcement over the years. The Office of Civil Rights (OCR) has been responsible for enforcing the HIPAA rules. Since the April 2003 compliance deadline, OCR has received more than 177,854 complaints and has initiated more than 884 compliance reviews.[1]

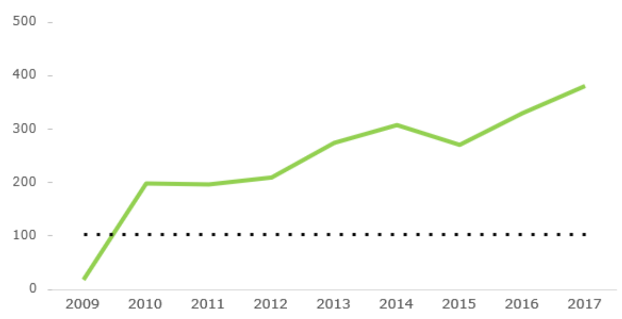
Health Information Technology for Economic and Clinical Health Act (HITECH)

HITECH was enacted in 2009 to promote the adoption and meaningful use of health information technology and to reinforce HIPAA rules. HITECH established breach notification requirements to provide greater transparency for individuals whose information may be at risk.

OCR's audit program

HITECH requires OCR to conduct periodic audits of covered entity and business associate compliance with the HIPAA rules. In 2011 and 2012, in order to assess compliance with HIPAA's requirements, OCR implemented a pilot audit program to examine the controls and processes implemented by 115 covered entities. OCR also conducted an extensive evaluation of the effectiveness of the pilot program. Drawing on that experience and the results of the evaluation, OCR implemented phase two of its audit program in 2016 under which both covered entities and business associates can be audited. The assessment can include or extend to hosted environments.[2]

Health care data breaches involving 500 or more records



Source: OCR Breach Porta

[1] Statistics published by OCR. Available at: https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html

[2] HIPAA Privacy, Security, and Breach Notification Audit Program. Available at: https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html

Considerations for cloud customers

Covered entities and business associates under HIPAA

Under HIPAA, a covered entity is a health care provider, a health plan, or a health care clearinghouse. A business associate is a person or entity who performs or assists in performing an activity regulated by the associated HIPAA rules, for or on behalf of the covered entity. If a covered entity or business associate engages a cloud service provider (CSP) such as Amazon Web Service (AWS) to store or process ePHI, the CSP itself is a business associate under HIPAA. It is important for customers moving to a public cloud environment to understand this distinction, because a business associate agreement (BAA) should then be enacted to define both privacy and security responsibilities of the covered entity and the business associate.

Business associate agreements

HIPAA requires a BAA between the covered entity and a business associate such as AWS. These agreements serve to define and limit the permissible uses and disclosures of ePHI, as appropriate. Examples of functions a business associate might provide include claims processing, billing, benefits management, member care, and provider data analysis. If a customer (covered entity or business associate) plans to use protected health information (as defined by HIPAA) within AWS services, the customer should first accept the AWS business associate addendum (AWS BAA). AWS services can be used with health care applications, but only services covered by the AWS BAA can be used to store, process, or transmit ePHI. Customers can review, accept, and check the status of their AWS BAA through a self-service portal available in AWS Artifact.

When it comes to deploying security and privacy technologies, public clouds have the benefit of economies of scale compared with private data centers.

Shared responsibility within the cloud

The AWS Shared Responsibility Model can be extended to the HIPAA control areas to assist with defining responsibilities.

Illustrative scenario: Health care provider hosts customer portal on AWS

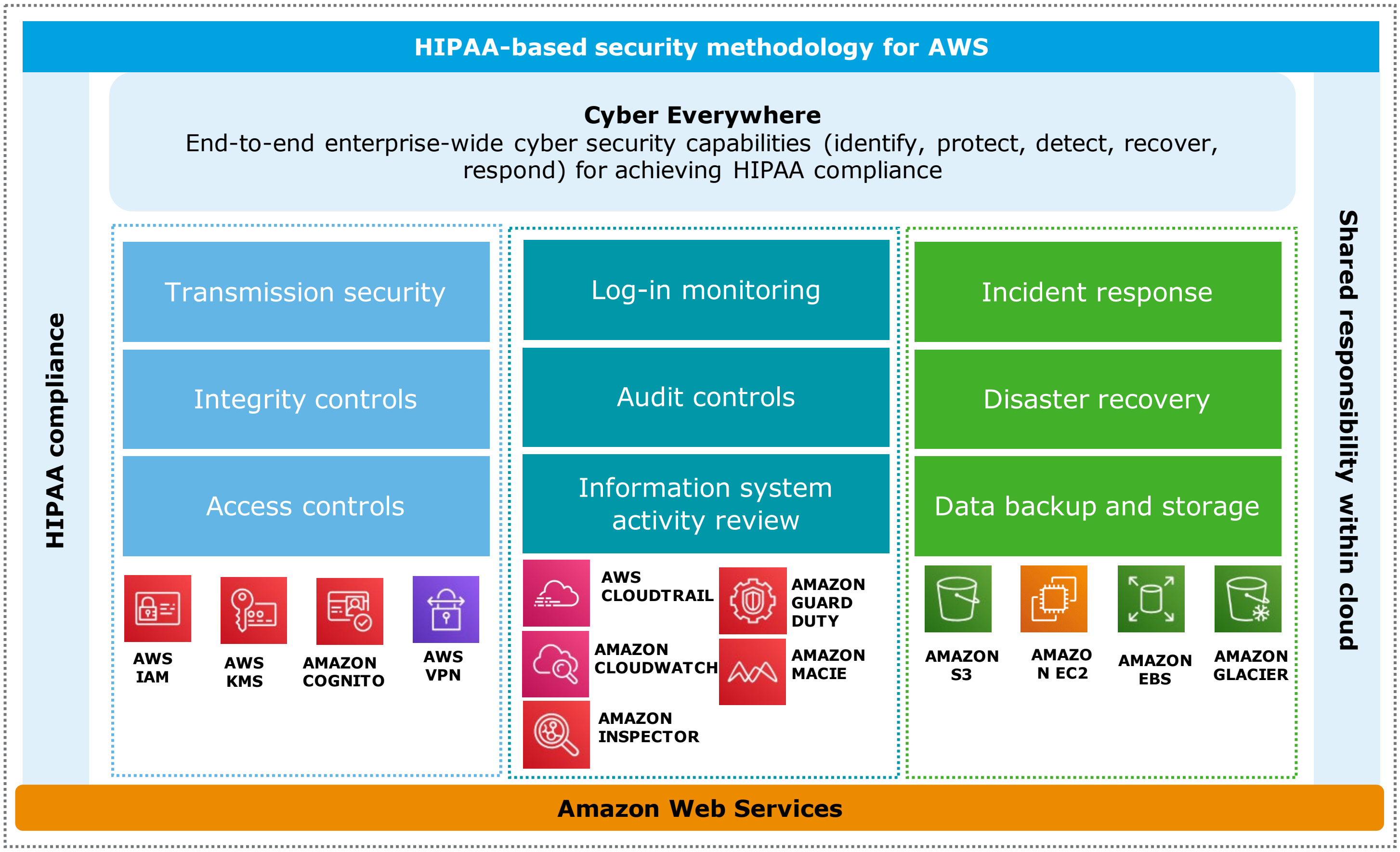
In this scenario, a health care provider and AWS are jointly responsible for meeting HIPAA security requirements.

Illustrative HIPAA control area	AWS responsibility	Health care provider responsibility
Access controls	Provide identity and access management capabilities for AWS services.	Implement policies and procedures for identity and access management that are consistent with the AWS BAA and HIPAA.
Audit controls	Enable logging and monitor capabilities for AWS services and ability to capture and log API actions against the AWS environment.	Employ auditing procedures that allow security analysts to periodically examine detailed activity logs or reports.
Incident response and disaster recovery	Provide and maintain disaster recovery capabilities for rapid recovery of IT infrastructure and data ensuring adequate durability and availability of services.	Develop a resilient architecture capable of responding to, and recovering from, incidents.

Architecting for HIPAA on AWS

Cyber Everywhere™

Deloitte used its deep cyber experience, technological innovation, enterprise-wide cyber capabilities, and leading industry experience to develop a HIPAA-based security methodology for AWS embedded with a range of controls that are relevant to enterprises in multiple industries. This methodology helps AWS customers meet the administrative, technical, and physical safeguards required under HIPAA using HIPAA-eligible and other AWS services.[3] Deloitte and AWS also developed whitepapers that deep dive on the topics of Identity and Access Management, Data Protection, IoT Security, and Network and Infrastructure security, which will cover the fundamentals of securing AWS broadly.



[3] HIPAA Eligible Services. Available at https://aws.amazon.com/compliance/hipaa-eligible-services-reference/

Establishing HIPAA compliant controls to secure data and systems

Effective controls across an organization's security infrastructure are imperative for creating a well-architected end-to-end security posture. The goal for architects and developers is to create an infrastructure capable of withstanding potential cyber-attacks. Once again, controls should align with safeguards documented within the HIPAA Security Rule

Assessing cybersecurity risk in the handling and storage of ePHI data

Understanding your responsibilities within HIPAA is important to securing ePHI within the AWS cloud, and a critical first step is the identification and assessment of cybersecurity risk. There are several sources of guidance available to assist entities in this effort. The Office of the National Coordinator for Health Information Technology (ONC) within the US Department of Health and Human Services (HHS) provides a detailed security risk assessment tool that covered entities can use to perform this risk assessment. The tool provides guidance on assessing the current posture of risks and safeguards for:

- Validating authenticated and authorized access to ePHI
- Checking ePHI transmission
- Maintaining integrity of systems and ePHI
- Validating secure transmission and storage of ePHI

The OCR, as a part of its audit program, has developed and published audit protocols[4] that can be used as a tool by organizations to conduct their own internal self-audits as part of their HIPAA compliance activities.

The National Institute of Standards and Technology (NIST) has also developed special publications[5] that provide guidance on HIPAA compliance, including NIST Special Publication 800-66: An Introductory Resource Guide for Implementing the HIPAA Security Rule.

Deloitte has extensive experience in providing HIPAA risk assessment and analysis services. Utilizing our proprietary assessment framework customized for cloud services, Deloitte can provide practical, actionable guidance and recommendations on meeting the requirements of the HIPAA security rule.

Whether an entity conducts their HIPAA risk assessment internally or works with an advisor such as Deloitte, they will need to gather information on how the business intends to use the cloud, and what applications and data will be migrated. The will also need to pay close attention to the HIPAA technical safeguards related to access, audit, integrity, and transmission security controls.

Secure transmission and storage of ePHI through integrity controls and encryption

The HIPAA Security Rule includes addressable implementation specifications for the encryption of ePHI in transit, in use, and at rest. Deloitte's approach uses AWS's native encryption tools. AWS offers a wide set of features and services to make encryption of ePHI manageable and easier to audit, including the AWS Key Management Service (AWS KMS). Customers can also take advantage of the encryption features native to HIPAA-eligible services such as AWS Simple Storage Service (S3). In addition to encryption at-rest, customers can enable encryption in-transit using TLS (encryption protocol) certificates, and they can leverage AWS Certificate Manager (ACM) for certificate management.

Deloitte has helped clients with network security and segmentation using AWS services such as Amazon Virtual Private Cloud (VPC). These services allow for segmentation of the network and data flows from non-ePHI-related compute and storage services. For developers, Amazon API Gateway is a HIPAA-eligible service that makes it easy to create, publish, maintain, monitor, and secure application programming interfaces (APIs) at scale. The APIs created with Amazon API Gateway expose HTTPS endpoints only, thereby providing encryption in-transit. Amazon API Gateway does not support unencrypted (HTTP) endpoints.

IAM, MFA, password management, and access authorization controls

Identity and access management (IAM) involves the strategies and methods used to authenticate and authorize actions that specific users can perform.

[4] An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, October 2008. Available at: https://csrc.nist.gov/publications/detail/sp/800-66/rev-1/final

[5] Architecting for HIPAA Security and Compliance on Amazon Web Services, January 2019. Available at: https://d0.awsstatic.com/whitepapers/compliance/AWS_HIPAA_Compliance_Whitepaper.pdf

IAM is a critical component of HIPAA security. Within an AWS environment, access management strategies and associated technical controls are needed at the AWS infrastructure layer, the operating system layer, and the application layer.[6] The HIPAA Security Rule documents addressable requirements for implementing authentication and authorization mechanisms to protect ePHI from being altered or destroyed in an unauthorized manner.

HIPAA contains requirements for covered entities to include procedures for creating, changing, and safeguarding passwords. AWS customers can manage passwords for account root users and for IAM users in their account. Customers can set a password policy on their AWS account to specify complexity requirements and mandatory rotation periods for their IAM users' passwords to prevent password re-use.

Deloitte has developed reference architectures for deploying privileged access management (PAM) solutions, which can serve as a starting point for PAM deployment in AWS. The architectures also provide blueprints for integration with AWS IAM and active directory/third-party identity providers (IdPs).

Leveraging the PAM solution enables effective management of root account passwords and system accounts. In addition to a PAM solution, enterprises should leverage AWS's multi-factor authentication (MFA) solution as an additional layer of security protection along with traditional user name and password credentials. Amazon Cognito can also be leveraged to extend native identity and access management controls within web and mobile applications.

Under HIPAA, covered entities should implement policies and procedures before granting access to PHI. Authorization in AWS is accomplished by permissions that are dictated by policies and then applying these to users via role mapping or group membership. A strategy for creating policies and assigning them to users is required to grant administrators the rights they need to perform their job functions while upholding a least-privilege approach. When an IdP is used with AWS, applying policies to users is achieved with roles. Users are mapped to roles within the IdP, and then they assume the role in AWS.

Amazon Cognito provides a simple and secure mechanism for authenticating users in an AWS environment. For an additional layer of authentication, customers can configure MFA with Cognito. Following authentication, users can assume the required IAM role to access the necessary AWS resources and APIs.

Recognizing resiliency as an important feature of HIPAA

Under HIPAA, covered entities must meet the Emergency Access Procedure requirement, which includes the need for availability in any HIPAA-compliant environment. To meet this requirement, covered entities must enable administrative controls, such as a data backup and disaster recovery plan. This contingency plan for protecting data in the event of a disaster should focus on the creation and maintenance of retrievable exact copies of ePHI. This involves maintaining highly available systems, keeping both the data and system replicated offsite, and enabling continuous access to both. In addition, implementing and testing identity and access management controls must be accounted for within the contingency plan. Secure authorization and authentication must be enabled, even during times where emergency access to ePHI is needed.

AWS provides tools and resources that customers can use to build scalable backup and recovery solutions. To implement a data backup plan on AWS, Amazon's Elastic Block Store (EBS) offers persistent storage for Amazon EC2 virtual server instances. These volumes can be exposed as standard block devices and offer off-instance storage that persists independently from the life of an instance[7]. To align with HIPAA guidelines, customers can create point-in-time snapshots of Amazon EBS volumes that are automatically stored in Amazon S3 and are replicated across multiple Availability Zones--distinct locations engineered to be isolated from failures in other Availability Zones. These snapshots can be accessed easily and can protect data for long-term durability.[8]

Amazon S3 also provides a highly available solution for data storage and automated backups. By simply loading a file or image into Amazon S3, multiple redundant copies are automatically created and stored in separate data centers. These files can be accessed easily (based on permissions), can be versioned, and are stored until deleted. Deloitte's framework empowers covered entities to develop a resilient AWS environment capable of responding to incidents by consistently backing up critical data.

[6] HIPAA Security Risk Assessment Tool, August 2019. Available at: https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool

[7] Using Amazon Web Services for Disaster Recovery, October 2014. Available at https://d1.awsstatic.com/whitepapers/aws-disaster-recovery.pdf

[8] Cyber Resilience – Building the "always-on" enterprise, 2017 available at https://www2.deloitte.com/content/dam/Deloitte/us/Documents/financial-services/us-advisory-cyber-resilience-deloitte-aws.pdf

Further, AWS has many options for databases. Customers can run their own database on Amazon EC2, use one of the managed service database options provided by the Amazon Relational Database Service (RDS), or leverage any of AWS's managed non-relational databases, such as DynamoDB, ElasticSearch, or Redis. Amazon RDS creates a storage volume snapshot of a customer's database instance, backing up the database instance, not just individual databases.

Leveraging AWS services, Deloitte can enable highly available and fault-tolerant architectures to meet HIPAA requirements. These can be harnessed through AWS service offerings that include decoupled architecture, high availability, redundancy, and security automation.

Being vigilant through auditing and monitoring

Auditing and monitoring controls are essential to meeting the requirements of the HIPAA Security Rule. Auditing controls are technical safeguards that should be addressed through technical controls by anyone who wishes to store, process, or transmit ePHI. Monitoring controls include procedures for monitoring log-ins and reporting discrepancies. A combination of services such as AWS Config, AWS CloudTrail, AWS Security Hub, Amazon GuardDuty, and Amazon CloudWatch create a cost-effective solution for auditing and monitoring resources in the AWS environment. AWS Config provides an assessment and audit of configurations of various AWS resources, while AWS CloudTrail captures API calls made to an account (either through the command line, Software Development Kit (SDK) or through the console user interface). CloudTrail logs can also be directly ported to an Amazon S3 bucket for further analysis by a third-party security incident and event management (SIEM) solution.

Continuously monitor to avoid HIPAA data breaches

Deloitte has helped clients build vigilant AWS environments that not only extensively monitor resources, but also send alerts when there is unusual or suspicious activity. AWS customers can collect logs from various sources and centrally store them in an S3 bucket, allowing for easy ingestion of logs into SIEM tools. SIEM capabilities such as alerting, interpreting, and parsing data can be leveraged through an established third-party vendor, Splunk, or they can be leveraged across several AWS services. Amazon Athena, for example, allows for analytical queries that parse data, while Amazon CloudWatch Event provides alerts for certain actions within the AWS environment. Deloitte uses CloudWatch Events to monitor for system events in near real time and created several auto-correction actions using AWS Lambda to enable compliance with baseline security configurations.

To increase the efficiency of alerts, the Deloitte approach leverages Amazon Macie. Macie uses machine learning to discover and classify unstructured, business-critical data, as well as analyze access patterns and user behavior within S3 buckets. While SIEM might alert customers about malicious activity anywhere in their accounts, because Macie can understand and classify data at-rest, it can determine which data is business critical and focus its alerts in these areas.

Monitor identity log-in attempts

The HIPAA Security Rule requires covered entities to implement procedures to monitor log-in attempts and report discrepancies. Customers who have enabled CloudTrail can see log entries associated with sign-in events, including the internet protocol (IP) address of the entity signing in and whether MFA was enforced for that sign-in. In addition to logging these events, CloudTrail captures successful sign-ins by users in IAM and root.

Analyze risks by identifying and remediating vulnerabilities

Under HIPAA, covered entities are required to conduct assessments of potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI held by them and by their business associates. Amazon Inspector is a HIPAA-eligible automated security assessment service designed to help improve the security and compliance of applications deployed on Amazon EC2. Clients can use Amazon Inspector to automatically evaluate applications for vulnerabilities or deviations from leading practices. After performing an assessment, Amazon Inspector produces a detailed list of security findings prioritized by level of severity. These findings can be reviewed directly or as part of detailed assessment reports that are available via the Amazon Inspector console or API.

Collect evidence and be audit ready

In designing an information system that is consistent with HIPAA requirements, customers should include auditing capabilities so that security analysts can test detailed activity logs or reports to see who had access, from what IP address, what data was accessed, etc.

Using Amazon EC2, customers can run activity log files and audits to the packet layer on their virtual servers, just as they do on traditional hardware. They can also track IP traffic that reaches their virtual server instance. Administrators can back up the log files into Amazon S3 for long-term, durable storage. AWS CloudTrail can be leveraged to monitor all API calls made and this can demonstrate to be a critical source for audits/forensic investigations. Deloitte's framework can enable customers to employ AWS services to track, log, and store data in a central location for extended periods of time, so it is available for use in case of an audit.

Get ahead of the curve

While moving to the cloud may provide information security benefits for customers, it does not discharge them from the duty under HIPAA to secure the data they possess. AWS provides myriad HIPAA-eligible services that can accelerate HIPAA compliance efforts.

Deloitte's implementation experience in cloud compliance and documented accelerators can help companies meet HIPAA compliance within AWS. Our approach includes performing a current-state cloud risk assessment, developing a detailed cloud security risk management program, and documenting administrative standards supporting the secure use of the AWS cloud, as well as designing, architecting, building, and testing technical safeguards within AWS.

The strength of the Deloitte/AWS relationship

aws partner network

Premier
Consulting Partner

- Security Competency
- Government Competency
- Financial Services Competency
- Public Sector Partner
- MSP Partner
- Life Sciences Competency

Our relationship brings together Deloitte’s extensive industry experience in cyber and enterprise risk management with the security-enabled cloud infrastructure of AWS. In 2006, AWS began offering IT infrastructure services to businesses in the form of web services—now commonly known as cloud computing. Today AWS provides a highly reliable, secure, scalable, low-cost infrastructure that powers hundreds of thousands of businesses in 190 countries around the world, with over a million active customers spread across many industries and geographies.

Deloitte can help organizations adopt AWS securely and establish a security-first cloud strategy. Deloitte is a leading information technology and advisory company. Deloitte is an APN Premier Consulting Partner and an AWS Security Competency Partner (Launch Partner) and was one of the first eight organizations globally to achieve the Security Competency as a launch partner. Deloitte’s vast experience in cyber risk, combined with its extensive experience with AWS and cloud technologies, enable us to provide end-to-end security solutions.

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