Google Cloud Whitepaper

August 2021

Two Guidelines from Three Ministries (2G3M)

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Introduction

Systems that include personal identifiable medical information (Medical PII), must comply with the following two guidelines:

1. Guideline for Safety Management of Medical Information Systems[1]
2. Safety Management Guideline for Information Systems and Service Providers Handling Medical Information[2]

These are collectively referred to as the "2 Guidelines from 3 Ministries" (2G3M). Google is committed to helping our customers meet their obligations under 2G3M by offering a secure foundation on which to build systems, tools to aid in the security of those systems and education on how to utilize these tools. This paper will explain how Google meets its obligations as well as how customers may use Google services to help meet their own obligations under 2G3M. This paper is intended to be for informational purposes only. Nothing in this whitepaper is intended to provide you with or should be used as a substitute for legal advice.

Requirements

Scope

The Guideline for Safety Management of Medical Information Systems defines compliance requirements for **users** of systems that handle medical PII such as hospitals, clinics, maternity homes, pharmacies, home-visit nursing stations, care providers, and medical information networks.

The Safety Management Guideline for Information Systems and Service Providers Handling Medical Information defines compliance requirements for **providers** of systems containing digitized medical PII. This includes Google Cloud services where they are used to build such a system.

These guidelines include the additional need to comply with the following regulations:

- Article 20 of the Act for the Protection of Personal Information (APPI), This defines security management measures for handling PII in order to meet the Safety Management for Medical Information Systems criteria.

[1] Version 5.1 published 2021 by the Ministry of Health, Labor & Welfare (MHLW)
[2] Published August 2020 jointly by the the Ministry of Economy, Trade and Industry (METI) and The Ministry of Internal Affairs and Communications (MIC)

- The Three Principles of Electronic Records (Authenticity, Readability and Storage Property) in accordance with the e-Document Law. In order to meet criteria for Digital Records set forth in The Guideline for Safety Management of Medical Information Systems (Chapter 7, 9)
- The External Storage Notice issued by the MHLW which defines requirements for storing Medical PII externally.
- Applications, servers, storage, etc. used to provide services should be installed in locations covered by the domestic law enforcement so that the documentation can be provided to government agencies in a smooth manner.

The Safety Management Guideline for Information Systems and Service Providers Handling Medical Information additionally requires service providers to conduct both risk management and risk communication.

In terms of risk management, the guideline requires service providers to clarify the data flow, identify risks, evaluate risks, and implement reasonable risk management measures.

In terms of risk communication, providers should disclose their risk management measures to medical institutions. This includes clarification on what actions the medical institutions can take to manage risk when using their services.

Risk Management Measures

Risk management measures required to meet theses requirements can be separated into the following four categories:

(1) Organizational Security

Organizational security refers to the creation, operation and documentation of an organization structure to manage security.

(2) Personnel Security

Personnel Security refers to controls that ensure staff maintain confidentiality and are trained on security measures.

(3) Physical Security

Physical Security refers to physical access controls such as barriers, locks and related measures to restrict who can access facilities.

(4) Technical Security

Technical security refers to digital access controls such as authentication, authorization, access controls as well as other security measures including logging, encryption, data leak prevention, vulnerability management and threat detection.

Shared Responsibility Model

Google Cloud is responsible for the security of the cloud infrastructure while our customers are responsible for the security of in their cloud environment.

Google Cloud has a relationship with its customers but not with the customer's end users. Google Cloud is not aware of the data our customers place in GCP or Google Workspace, nor do we act as handlers of that data. The only interaction Google Cloud has with any customer data in our systems is to execute the services our customers select. Customers must take appropriate measures to secure the data they place in cloud services.

Below are common measures for each risk management category. In the sections that follow we will explain how Google Cloud provides a secure foundation covering its side of the shared security model. Then we will introduce Google Cloud products and services that help customers with each security measure so that they can comply with their side of the shared responsibility model.

Organizational Security Measures

Requirement	Security Concept
Clarify roles & responsibilities of persons involved in medical PII handling.	Identity Data Governance
Have a mechanism for detection and reporting of medical PII incidents.	Threat Detection
Maintain records of medical PII handling including access & changes	Logging Data Governance
Maintain records on medical PII under management including its nature, purpose, consent and who has access.	Data Governance Access Controls
Be able to investigate a potential leak and report to relevant authorities the facts.	Logging Threat Detection

Be able to audit medical PII handling activities	Logging Data Governance

Personnel Security Measures

Requirement	Security Concept
Ensure supervision of those handling medical PII	Logging Contracts Assurance
Provide training on the handling of medical PII	Training & Consulting
Ensure employees maintain confidentiality	Training & Consulting

Physical Security Measures

Requirement	Security Concept
Implement management & restrictions on medical PII handling areas	Infrastructure Identity Data Governance Data Transformation
Put in barriers on medical PII handling areas such that access or viewing by unauthorized persons is not possible.	Infrastructure Data Transformation
Ensure prevention of physical theft of medical PII in storage & in transit	Infrastructure Data Transformation
Implement an irreversible method of medical PII data deletion	Data Deletion

Technical Security Measures

Requirement	Security Concept
Limit access to medical PII to only those who need access	Identity Access Controls Data Governance Data Transformation

Limit access to minimal medical PII required for each role	Access Controls
Ensure each medical PII handler can be identified and authenticated	Identity
Implement network access controls to limit potential access	Access Controls
Utilize security technologies to protect systems from unauthorized access	Endpoint CI/CD Pipeline Partners Solutions
Maintain systems at latest secure state by auto-updates	CI/CD Pipeline Managed Services
Analyze logs and detect threats in them	Threat Detection
Continuously evaluate systems for vulnerabilities	Risk Detection
Protect medical PII in storage and transport	Data Transformation

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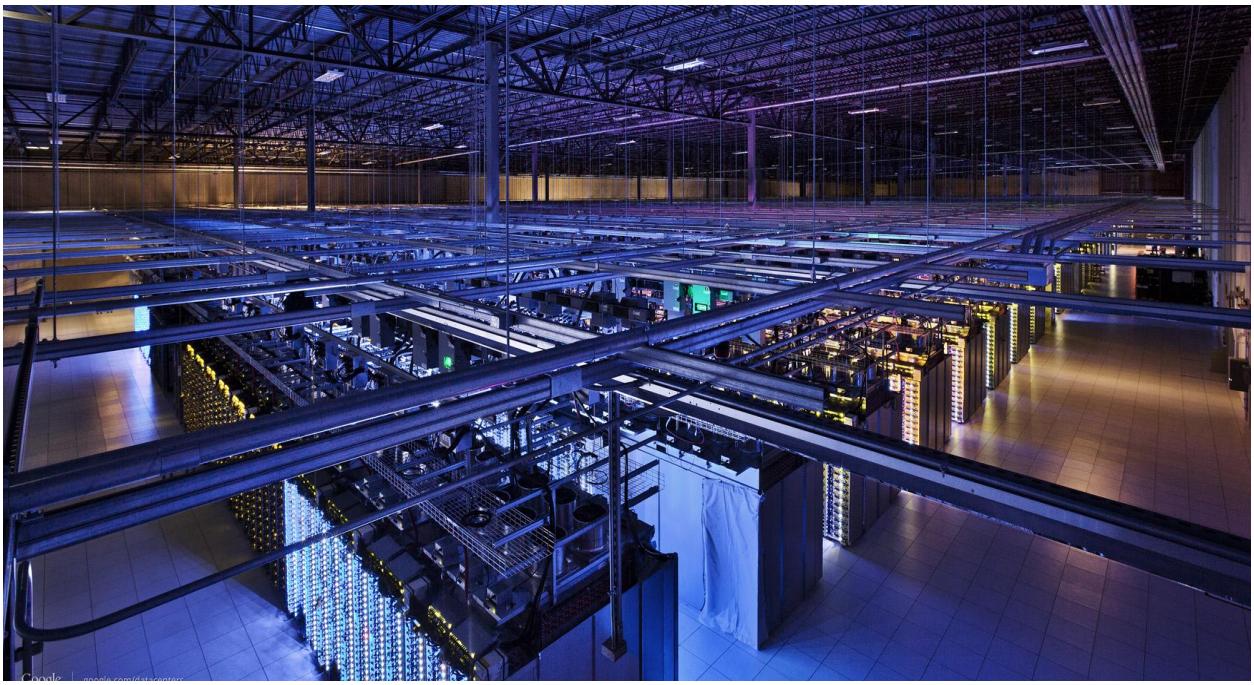
Google Cloud Security

Security in our infrastructure

Google operates global infrastructure designed to provide state-of-the-art security through the information processing lifecycle. This infrastructure is built to provide secure deployment of services, secure storage of data with end-user privacy safeguards, secure communications between services, secure and private communication with customers over the Internet, and safe operation by administrators. Google Workspace and Google Cloud Platform run on this infrastructure.



We designed the security of our infrastructure in layers that build upon one another, from the physical security of data centers, to the security protections of our hardware and software, to the processes we use to support operational security. This layered protection creates a strong security foundation for everything we do. A detailed discussion of our Infrastructure Security can be found in our Google Infrastructure Security Design Whitepaper.

Security in our contracts

Our GCP and Google Workspace data processing terms clearly articulate our security & privacy commitments to customers. We have evolved these terms over the years based on feedback from our customers and regulators. Core to this is the understanding that any data that a customer puts into our systems will only be processed in accordance with the customer's instructions.

Google Cloud also commits to take security measures to ensure the confidentiality, integrity and availability of our systems. These are laid out in some detail in the agreement along with a further commitment that any changes we make to our security measures going forward will not degrade security. Our goal in stating this is to provide our customers continuous security improvement.

Security assurance

Google Cloud Platform and Google Workspace undergo several independent third party audits to test for data safety, privacy, and security. Our third party audit approach is designed to be comprehensive in order to provide assurances of our level of information security with regard to confidentiality, integrity and availability. Customers may use these third party audits to assess how Google's products can meet their compliance and data-processing needs. The relevant third-party certifications for our customers subject to the 2G3M are listed below. For more information see our Compliance Resource Center.

ISO/IEC 27001

ISO/IEC 27001 is a security standard that outlines and provides the requirements for an information security management system. The 27001 standard lays out a framework and checklist of controls that allow Google to ensure a comprehensive and continually improving model for security management. Google Cloud Platform and Google Workspace are certified as ISO 27001 compliant.

ISO/IEC 27018

ISO/IEC 27018 is an international standard of practice for protection of personally identifiable information (PII) in Public Cloud Services. Google Workspace and Google Cloud Platform are certified as ISO/IEC compliant

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Google Cloud Services

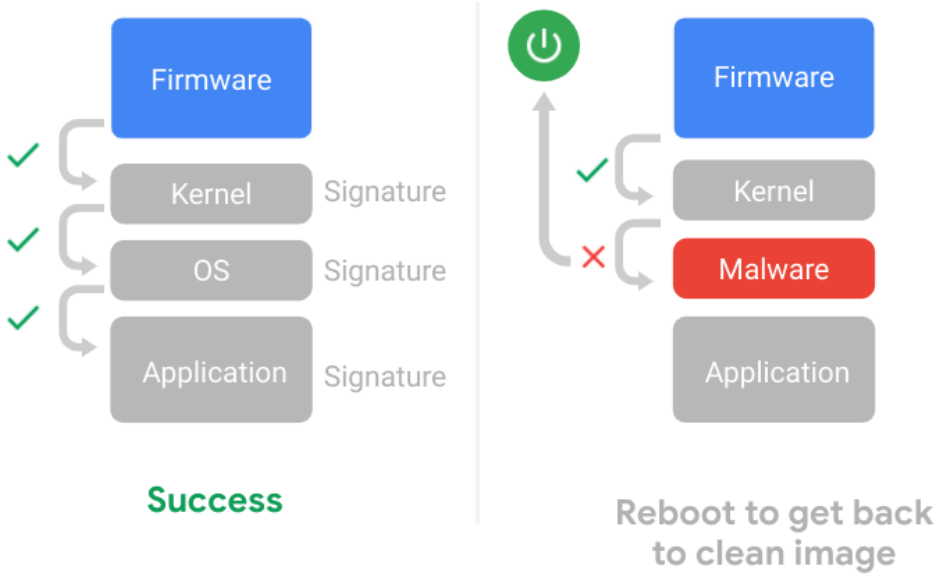
Google Cloud provides a number of products and services to help customers meet their obligations under 2G3M.

Endpoint

In order to securely handle medical PII, one must access that medical PII using a secure endpoint. At Google, we have developed browser and OS technologies as part of the Chrome product family. These products have a very small attack surface in order to prevent common threats from taking hold on an endpoint. These solutions are available to our customers as Chrome Browser, Chrome OS and ChromeBooks centrally managed by Chrome Enterprise.

Chrome Browser is a minimal browser that automatically updates itself. It uses SafeBrowsing to check URLs against a database of known bad URLs and can warn or block sites that are deemed high risk. Chrome tabs are sandboxed. Even I-frames in a tab are sandboxed. Chrome itself is isolated on the OS and has no access to other processes.

ChromeBooks run Chrome OS. Chrome OS is a read-only OS so malware has no way to infect or change the system files. ChromeBook's maintain 2 copies of Chrome OS; a working copy and a standby copy. Failure to boot the working copy will pull up the standby copy. This is beneficial for upgrades which are done on the standby copy and then it becomes the working copy on reboot. So not only do you get security but you get no downtime for upgrades. ChromeBooks have a Titan-C chip that will verify the firmware, OS and browser code. Should it detect a change it will not boot that version of the OS.



ChromeBooks encrypt data at rest but Chrome users tend not to have much data on their ChromeBooks since most of their data is in Google Cloud Services such as Google Workspace. Thus there is nothing to steal and even if ransomware could take hold, it would have nothing to ransom.

Chrome Enterprise Upgrade is a cloud based management system for having consistent administration over the Chrome OS environment. Software deployment, upgrades and Chrome settings can be configured for your entire fleet from one single console. Using Chrome Enterprise and ChromeBooks customers can easily meet and greatly exceed the PPC's expectations for security controls on the endpoint.

Identity

Identity is the backbone of access control. Google Cloud supports multiple identity providers as well as our own Cloud Identity.

Cloud Identity uses machine learning to detect unauthorized access and can even detect and block unauthorized intruders using the correct password.

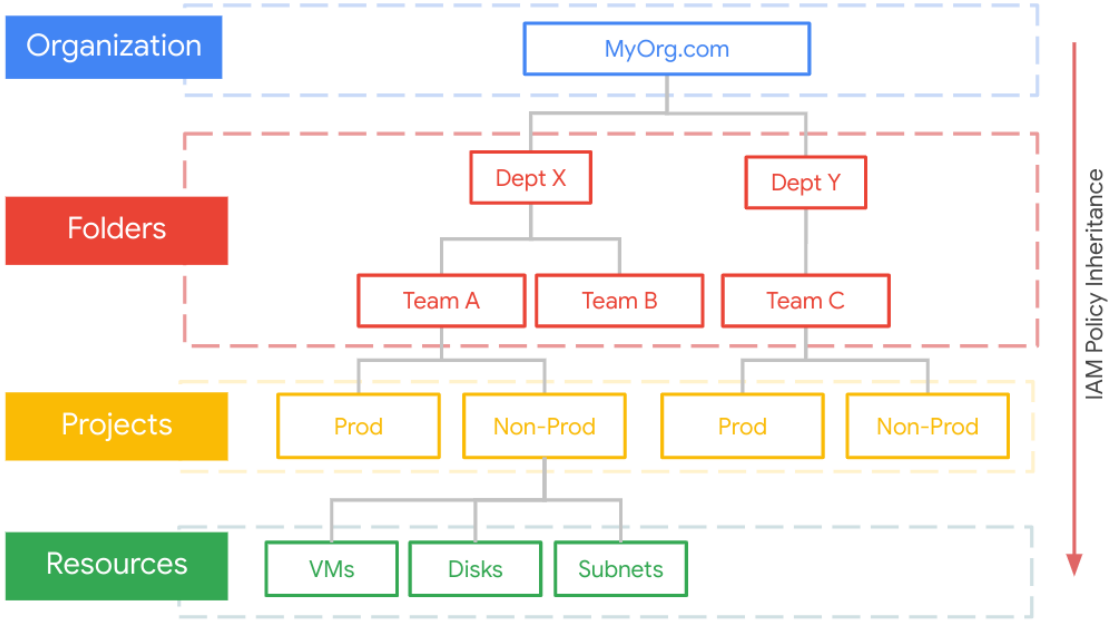
Cloud Identity also supports the strongest forms of account protection including multiple 2FA options such as FIDO compliant security keys. Googlers use security keys on our own accounts to provide stronger identity protection and to prevent phishing attacks. We recommend our customers do the same.

Access Controls

In Google Cloud all services require authorization to use. Authorization is managed primarily in IAM. IAM allows you to grant roles to members such as users and groups. These roles are made up of fine grained permissions. Curated roles are provided and customers can create custom roles as needed.

Conditions can also be applied to roles. So for example a contractor that is only supposed to work 9 to 5 can have a condition added to the roles attached to them that limits their access to just 9 to 5.

GCP has a resource manager where you can set up a folder tree to organize your projects. Access controls can be managed at any layer of the hierarchy and inherited down which is beneficial for good governance. Medical PII specific folder(s) could be established and access controls applied there so as to have them consistent across all projects in that folder.



One of the biggest challenges for enterprise customers is not granting access but rather taking it away when it is not needed or excessive. IAM Recommender uses machine learning to see what permissions are being used and which are not and then makes recommendations to remove excess access. Policy analyzer can help you figure out who has access to what, which is helpful in an audit situation.

Some Google Cloud services include service specific access controls that exceed what IAM can offer. For example in BigQuery you can set up limited views of data tables and you can filter rows and columns meeting certain criteria. This can be very useful for minimizing the medical PII data analysts can see or filtering it out entirely.

In Google Workspace you can apply access controls on services based on the context of the user's identity and device. You can define at the file level who can read, comment or edit each individual file or folder.

Network Access Controls

In a traditional network, including most cloud providers, firewall rules for network access control can only be applied at choke points. In Google Cloud firewall rules are much more flexible. They can be applied to a single VM, tagged assets, assets that share the same service account or a combination of factors.

Instead of applying the same rules to every project, common rules can be applied across projects at folder or organization level using hierarchical firewall policies.

The rules affecting an asset can be analyzed both from the command line as well as in the Network Intelligence Center.

It is also important to control access to service APIs. In Google Cloud you determine what APIs you want to turn on or off. Furthermore you can place a perimeter around the APIs of your project using VPC Service Controls. VPC-SC can block data egress and place conditions on ingress.

Application Access Controls

Google Cloud provides the infrastructure for our customers to build their applications. The access controls inside those applications are part of the application logic the customer provides. However the access to those applications can leverage our context aware access system called BeyondCorp Enterprise.

BeyondCorp Enterprise allows you to define which users can access which applications under which conditions. Those conditions can be related to the situation (eg time), the device (eg corporate managed) and the user's identity and authentication (eg MFA). This adds stronger controls that simple identity to systems with medical PII.

BeyondCorp Enterprise also has the ability to examine data uploads/downloads in Chrome and determine if certain data (eg. medical PII) is included. It can then take a predefined action such as to block that data movement.

Logging

Google Cloud offers extensive audit logging for services. Network logs provide both network and security operations with in-depth network service telemetry. VPC Flow Logs can be used for network monitoring, forensics and real-time security analysis. Packet level capture can be done with Packet Mirroring for content analysis or to feed into a Network Intrusion Detection System. Firewall Rules Logging allows you to audit, verify, and analyze the effects of your firewall rules. NAT and DNS logs are also available for threat analysis.

Google Cloud Platform has Cloud Audit logging to log API activities including who did what, where and when. Data access logs can provide additional details at the data level and are especially useful for data management services. Google cloud does not handle customer data but if a customer specifically instructs us to access their data as part of support troubleshooting then that access is also logged and those logs can be made visible to customers via Access Transparency.

Cloud Operations provides a centralized tool for logging that can take in logs from a multitude of sources including custom logs sent from OS level agents, Fluentd, REST APIs, client libraries or 3rd party applications. Logs can be analyzed in real time with Logs Viewer, or you can visualize and alert on your logs with logs-based metrics and Cloud Monitoring.

GCP provides a variety of log storage and retention options to meet both security & compliance requirements. System logs and data access logs are retained for 30 days by default or optionally up to 10 years. Admin logs are retained for 400 days in locked storage. Log data is immutable, encrypted at rest and monitored via Access Transparency.

Google Workspace includes extensive logging capabilities for everything from administration to users to services to devices. These logs can be fed to Cloud Operations in GCP for consolidated analysis.

Threat Detection

Security Command Center (SCC) in Google Cloud provides wing to wing risk management for Google Cloud customers. One component of SCC is threat detection. SCC will compare logs to known indicators of compromise as well as suspicious behaviors and surface alerts. Those alerts can be acted on automatically by triggering cloud functions. So for example a VM detected to be compromised could be imaged and isolated on the network all automatically.

Logs can also be exported from Google Cloud to Chronicle or 3rd party SIEMs like Splunk for further threat analysis or correlation with non-cloud logs to see the bigger enterprise threat picture. Chronicle continuously compares all your logs to a huge database of indicators of compromise (IOC) and surfaces any matches. Chronicle can search petabytes of logs in a single second.

Managed Services

Maintaining systems is complicated, costly and distracting for most customers. We recommend using managed services which we maintain for you. As you can see by the diagram below the more managed a service is the more you can focus on your data and leave the responsibility for the underlying infrastructure to Google.

Even in cases where compute services are required, we recommend taking advantage of the most managed form. For example a simple function can be run in cloud functions without any need for further management. Containers can be managed in GKE with node auto-upgrades which decreases the maintenance burden.

The team that manages the security of GKE is the same team that designed and wrote large parts of K8s identity, authorization and security policy code. The same team that led or contributed to the investigation, triage, patching, and notification of every serious K8s vulnerability since day 0. So you could not pick a better team to handle K8s management.

Secure CI/CD Pipeline

One way a threat actor might abuse medical PII is to alter the code that is loaded into an application handling medical PII. This is why having security as part of your continuous integration and delivery pipeline (CI/CD) is so important. We recommend having a healthy code review process in place and have provided a guide to the public where we share our own practices and thoughts on this subject.

Google Cloud provides COS (Container Optimized OS) for nodes. Container-Optimized OS's small OS footprint minimizes security exposure while still containing essential built-in security features like a minimal read-only root file system, file system integrity check, locked-down firewall, and audit logging. Automatic updates patch security vulnerabilities for you and in a timely manner, further reducing your risk of compromise. Shielded GKE is built on hardware with a Titan chip that sets off a provenance validation sequence from host bootloader right up to the guest COS kernel in order to ensure end to end supply chain security.

Ensuring vulnerable containers are detected and addressed is key. Google Cloud can scan your containers added to Container Registry and report any defects.

Container policies can be set using Anthos Container Policy Controller. This is great for governance and can be used to ensure that a project team doesn't deploy containers with rights exceeded that allowed by company policy.

Using Binary Authorization it is possible to define signatures for passing various steps of the CI/CD pipeline and these signatures can be checked as a condition of deployment. This not only ensures all steps were passed but also keeps unauthorized code from being deployed to production.

Google Cloud infrastructure can also be managed and deployed as code. Google Cloud has published reference architectures and guides to help customers get started with these techniques. The Google Cloud Data Protection Tool-kit Guide is specifically aimed at Healthcare and Life Sciences workloads. The toolkit combines best practices and security configurations for deploying Google Cloud resources to store and process sensitive data.

Risk Detection

Application code can also be checked while running by Web Security canner which looks for common misconfigurations and vulnerabilities targeted by OWASP. Our premium offering even scans GCP looking for web applications and can surface shadow applications that may have been built without authorization.

Security Command Center checks your entire Google Cloud organization for misconfigurations and vulnerabilities and then maps those against a list of your cloud assets. In fact SCC will map risks and threats not only to assets but also to different compliance frameworks such as ISO

27001, PCI DSS and the CIS best practices for GCP. This allows you to meet your obligations to prevent and detect incidents affecting medical PII you place in GCP.

In Google Workspace you can get insights into security events and metrics that demonstrate your security effectiveness in a single, comprehensive dashboard called Security Center. From there you can Identify, triage, and take action on security and privacy issues such as deleting malicious emails across your organization and examining file sharing to spot and stop potential data exfiltration.

Data Governance

Keeping track of medical PII can be a challenge for organizations as different systems and functions in the company make different copies. Data Governance is key and Google Cloud can help with this. By data governance we mean:

1. Discover medical PII
2. Label medical PII
3. Apply rules to medical PII

Data Catalog can use DLP API to find and apply metadata labels to your medical PII regardless of its location. Those labels can be used to apply rules so as to screen in/out certain data in processing jobs or data analytics systems.

Customers can select the region to run their workloads including two regions under Japanese jurisdiction.

Google Workspace also has DLP capabilities which administrators can configure to detect medical PII in files and take actions such as alerts or set restrictions on them such as to restrict outside sharing.

Data Transformation

Medical PII can be hidden or removed at different handling points using transformation techniques. DLP API can remove medical PII by masking or redacting the medical PII.

ID	Job Title	Phone	Comments
359740	Senior Engineer	307-964-0673	Please email them at jane@imadethisup.com
981587	VP, Engineer	713-910-6787	none
394091	Lawyer	692-398-4146	Updated phone to: 692-398-4146
986941	Senior Ops Manager	294-967-5508	none
490456	Junior Ops Manager	791-954-3281	Tried to verify account with their SSN 222-44-5555

There may be times when you both need to use medical PII but also need to hide the medical PII. There are two ways to do that. In the case of using it as a field in a data table you can use DLP API to replace the medical PII with unique tokens (tokenization). If you only need to hide the data in storage or transit but would like to unhide it later then encryption makes more sense.

Google Cloud offers many encryption options. Key Management Service (KMS) can have cryptographic operations as a managed service that you access via an API. Under Cloud HSM you can use the same KMS front end knowing the backend is a FIPS-2 Level 3 certified HSM. In fact you can even use the KMS front end with an External Key Manager if you wish to separate duties.

Google Cloud also has Cloud Healthcare API to support unique medical data types such as DICOM instances and FHIR resources. Cloud Healthcare API can find sensitive PII in these formats and handle de-identification to mask, delete, or otherwise obscure the data. This can empower medical institutions:

- When sharing health information with non-privileged parties
- When creating datasets from multiple sources and analyzing them
- When anonymizing data so that it can be used in machine learning models

Data Deletion

Customer data in Google Cloud belongs to the customer and the customer can select to delete it at any time. Doing so makes the data immediately unavailable and kicks off wipe out procedures that extend to the various service components involved. These wipe out procedures can take up to 180 days. These procedures once complete provide for irreversible destruction of the data. Details are in the following whitepapers for GCP & Google Workspace.

Training & Consultation

Google Cloud has a wide range of training and consultation support for our customers such as:

- Pre-sales staff to walk you thru our services and help choose the right ones
- Training and education staff to train your team
- Cloud on Air and Youtube Videos
- Online training partners so you can train on your own schedule
- Certification program to level set required skills
- Online documentation in multiple languages

- Qwiklabs to practice using our services
- Post-sales consulting services
- System integrator partnerships to build and manage solutions at scale
- A lively online community of blogs, articles, videos and chat rooms to share ideas and derive inspiration

Partner Solutions

Google Cloud has partnered with a wide variety of security solutions companies to make their solutions available to our customers either via the Google Cloud Marketplace or other partnership agreements. In addition we provide basic compute services that can support most security solutions regardless of whether they are a Google Cloud partner or not.

Our sales team is happy to hear your security requirements and provide consultation on which partner solutions best match your use cases.

Further Information

Google as a **Provider** has provided a Control Mapping document for *The Safety Management Guideline for Information Systems and Service Providers Handling Medical Information*. This shows how our controls map to each control requirement in the guideline. This includes controls that have been certified by third-party audits, including international standards such as ISO 27001, ISO 27017, and ISO 27018. Please refer to the manual for details of Google's for more details.

For more information on Google's security or compliance response, please refer to:

- Control Mapping (English)
- Protecting Healthcare Data on Google CloudS
- Google Cloud Security and Compliance Whitepaper
- Google Infrastructure Security Design Overview