Government Blockchain Association

Healthcare Working Group

Healthcare Supplement

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Approvals

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Contents

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1 Introduction

1.1 Purpose

This document acts as the guide for the Blockchain Maturity Model (BMM)[1] supplemental review for solutions that are designed to support healthcare services (specific to the healthcare domain).

1.2 Scope

This document is applicable to systems that employ blockchains or Distributed Ledger Technology (DLT) where data containing health information such as images, diagnostics, caregiver or administrative documentation, or anything related to healthcare services, including patient or caregiver identity, financial information, plans of care, population health, quality metrics, research data or any information that can be defined as Protected Health Information (PHI) under HIPAA[2], or Sensitive Personal Data under GDPR[3] is created, shared or transacted upon. This scope is supplemental to the overarching scope of the BMM.

1.3 Use

When performing a BMM assessment of a healthcare solution, the lead assessor will review the supplemental requirements in this document with the Solution Point of Contact (SPoC)[4] to determine which requirements are applicable as "Domain" requirements. Achievement of Domain requirements allows for the assessment as a healthcare solution and additional designation of "Healthcare" to the BMM Rating.

The Lead Appraiser and the SPoC review the **Appendix D: Solution Transaction Modality / Healthcare Requirements Matrix** below and identify the Solution Transaction Modality(ies) that are applicable to the solution being assessed along with the Requirements that the implementing organization or the solution provider have deemed necessary for the assessed system to operate in a live environment. Next, all the requirements that are marked "R" (Required), "A" (needs Assessment for Applicability) or "O" (Optional) are reviewed to determine the scope of the assessment.

The result of the analysis is recorded in the appraisal plan. The Lead Assessor and the SPoC both sign the appraisal plan to reflect their agreement on the BMM supplemental requirements and scope of the appraisal.

1.4 Assessment Rating Considerations

For each agreed requirement, the solution will be deemed to **meet** or **not meet** the requirement. A justification for the assessment will be documented and recommendations for improvement will be provided. It is important to note that the solution deemed to meet or not meet the supplemental requirements will be no greater than the BMM assessment ranking. E.g., if the

[1] https://gbaglobal.org/blockchain-maturity-model

[2] https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html

[3] https://commission.europa.eu/law/law-topic/data-protection/reform/rules-business-and-organisations/legal-grounds-processing-data/sensitive-data/what-personal-data-considered-sensitive_en

[4] See BMM Overview Glossary

maturity ranking or relevant capability ranking is a "2", then the supplemental requirements are assessed as applicable to level "2". If the solution advances in its capabilities to a higher BMM ranking, the supplemental requirements will need to be reassessed in accordance with the higher ranking.

1.5 Future Use and Continuing Process Improvement

Since technology and innovation are constantly changing, this document and its guidance will evolve over time. It is considered a "living document" that will include new requirements, use cases, and other information as GBA Healthcare Working Group members, industry stakeholders and technology professionals progressively add inputs, commentary, and new perspectives.

2 Solution Transaction Modality

The following characteristics define how the proposed solution interacts with stakeholders and participants. These characteristics specify the broad intention or focus of the blockchain-featured system within the organization, which in turn, determines the type of governance, compliance, and management that might be generally required of a mature system. The solution characteristics are independent of the specific use case(s) the blockchain-featured system is created to address, and a specific use case may fit into more than one Solution Transaction Modality.

2.1 Patient Facing Systems

The solution utilizes workflows that interact directly with the patient. These systems may enable users to transact on PHI including, but not limited to, patient demographic information, patient financial information, or plans of care.

2.2 Internal Systems

The solution utilizes workflows that interact with the internal administration of an organization. This may or may not include physicians depending on the use case.

2.3 Cohort Systems

The solution utilizes workflows that interact with professional organizations external to the health care practice where the blockchain-featured system is implemented. A cohort system could be a neighboring hospital, an external laboratory, an insurance company, or any other organization with whom information may be shared.

2.4 Reporting Systems

The solution utilizes workflows that are meant to share reports regarding productivity, trends, regulatory compliance, revenue generation, population health data, or other information. In this context, a solution defined as a *Reporting System* may be used for internal reporting within an organization or external reporting to a governmental or regulatory entity. This transaction type generally does not connect with patients.

> **Note:** Different healthcare-centric use cases are described in **Appendix C: Healthcare Use Cases** and are meant to fit generally into one or more Solution Characteristics. For example, a use case for **Case Management** or **Document Management** could be defined with the Patient-Facing Systems Solution Characteristic if the process workflows interact with the patient receiving health

services, while the **Materials Management** or **Medical Device Supply Chain** use cases could be described as Internal Systems since the process workflows typically interact within an organization's in-house administration.

3 Requirements

These requirements cite examples of best practice procedures that a healthcare organization might currently follow within their due diligence processes to research, vet, analyze and select technology solutions to incorporate within their enterprise. Such requirements vary between systems and can be based on regulatory requirements, specialized service delivery, system security, in-place system architecture, geography, and other factors.

3.1 3rd Party ID Validation

The solution shall have connections to credentialing authorities that can validate the authenticity of credentials they discretely assign. An example would be a connection to the government issuing authority for an identification card, an academic organization such as a university, or an insurance organization. Whoever issues the credential can be referred to for validation of the credential's authenticity.

3.2 Auditing and Reporting

The solution shall provide reconciliation capabilities for all digital asset transactions and data states including data creation and provenance, access, transfer, and storage. Information is provided in a read-only fashion by default.

Note: while auditing and reporting capabilities and requirements may differ between organizations and systems, *standard industry audits* include, but are not necessarily limited to, HIPAA Compliance audits, Security Risk Assessments, Meaningful Use audits, Data Accuracy and Integrity audits, Coding and Documentation audits, Clinical Documentation Improvement (CDI) audits, Charge Capture audits, Revenue Cycle audits, Utilization Review audits, Data Governance and Privacy audits, Electronic Health Record (EHR) audits, and Recovery Audit Contractor (RAC) Audits. The *Auditing and Reporting* function described in this requirement primarily refers to the definition above and may or may not describe a solution's ability to provide information for, or participate in, industry audits.

3.3 Credential Management

The solution verifies the validity of a caregiver's credentials including education, training, licensure, board certifications, fellowship programs, certifications or specialized training against the credential issuer's records. Once the credential is verified, the validation information can be provided on demand.

3.4 Delegated Authority

The solution provides mechanisms for a user to assign agency to a third party for predefined decision-making, execution of processes, receipt of information, and other consent-related activities on their behalf.

Example: *The solution provides for the delegation of authority and access to an individual's record by a trusted third party such as a parent/child relationship, or an entity that has power of attorney. Controls like KYP should be implemented to validate the identity of the trusted third party.*

3.5 Intermediary Provision

The solution allows a user to assign administrative responsibility to an agent of their choosing. This is used in conjunction with Delegated Authority.

Example: similar to Delegated Authority, the solution provides for a trusted third party to manage, interact, and transact with an individual's (or organization's) digital assets as a proxy. This is treated as a feature for physicians or healthcare organization leaders to entrust access/transaction authority to an administrator.

3.6 Role-Based Access Control (RBAC)[5]

The solution utilizes a security model that restricts system access based on predefined roles and permissions rather than on users' individual identities.

3.7 Data Migration

The solution offers features for relocation or ingestion of legacy data into its platform.

3.8 Interoperability

The solution offers features for interconnection and process participation with legacy and in-place healthcare IT systems and protocols.

Note: while *Interoperability* is addressed within the BMM Content and Structure section[6], this requirement specifically refers to the solution's need to integrate within an organization's current architecture using its implemented structure (for example, using a message Interface Engine), protocols (such as HL7), or standards.

3.9 HIPAA Compliant[7]

The solution adheres to the regulations and requirements outlined in the HIPAA (Health Insurance Portability and Accountability Act) Privacy, Security, and Breach Notification Rules. HIPAA is a **US federal law** that establishes standards and safeguards to protect the privacy and security of individuals' Protected Health Information (PHI). The assessed organization has systems in place to address and implement regulatory compliance for this requirement.

3.10 GDPR Compliant[8]

The solution follows the regulations and requirements outlined in the GDPR (General Data Protection Regulation) which governs the processing and protection of personal data of individuals within the **European Union (EU) and European Economic Area (EEA)**. The assessed

[5] Role-based Access Controls: https://en.wikipedia.org/wiki/Role-based_access_control
[6] https://gbaglobal.org/blockchain-maturity-model Section 4.1.3
[7] Health Insurance Portability and Accountability Act of 1996: https://aspe.hhs.gov/reports/health-insurance-portability-accountability-act-1996
[8] General Data Protection Regulation: https://gdpr.eu/data-privacy/

organization has systems in place to address and implement regulatory compliance for this requirement.

3.11 Selective Disclosure

The solution offers mechanisms for data owners to share information at a granular level with specific, identified receivers in a controlled and auditable fashion. This requirement enhances privacy, confidentiality, and data security.

3.12 HL7[9]/ FHIR[10] Capable

The solution offers features to transmit data between health information systems using HL7 (Health Level Seven) standards in the exchange, integration, sharing, and retrieval of electronic health information.

FHIR (Fast Healthcare Interoperability Resources) is an HL7 subset protocol that uses modern web technologies such as JSON, XML, and RESTful APIs to enable easier and more flexible health data exchanges.

3.13 Know Your Patient[11] (KYP)

The solution offers features that provide relevant information to a caregiver in the execution of their Know Your Patient (KYP) process.

KYP focuses on gathering essential information about the patient in a timely fashion to ensure accurate identification, appropriate treatment, and safe care delivery. Implementation of this process is meant to diminish medication or treatment errors, improve care coordination, enable informed decision-making by the caregiver, and help healthcare organizations maintain accurate records.

3.14 ISO 13485[12]

The solution follows the voluntary regulations outlined in the **ISO 13485** standard which contains a comprehensive quality management system for the design and manufacture of medical devices. The current ISO 13485 edition was published on 1 March 2016 and supersedes earlier published versions.

3.15 Handles PHI[13]

The solution allows users to transact on information classified as PHI regardless of vantage point (patient to health or insurance service provider, provider to patient, provider to provider, etc.).

3.16 Handles X12[14]

The solution follows X12 protocol standards in transmission and handling of structured business data, including healthcare-related information, in a consistent format. The X12 standards are

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[9] Health Level Seven - https://www.hl7.org/about/
[10] Fast Healthcare Interoperability Resources - https://www.healthit.gov/topic/standards-technology/standards/fhir-fact-sheets
[11] Know Your Patient - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4000752/
[12] https://www.iso.org/iso-13485-medical-devices.html
[13] Protected Health Information - https://en.wikipedia.org/wiki/Protected_health_information
[14] Accredited Standards Committee X12 (ASC X12): https://www.x12.org/

widely used in the healthcare industry to facilitate the electronic exchange of administrative, financial, and clinical information between healthcare providers, payers (such as insurance companies or government agencies), and other entities involved in healthcare operations.

Appendix A: Healthcare Services Fundamentals

While specific approaches to patient service provision may vary across healthcare facilities and providers, it is generally agreed that the phases involved in the health care services delivery process occur between three primary stakeholder groups: the **Patient** or healthcare consumer, the **Provider**, which is the clinician, healthcare organization (i.e., hospital or clinic) or licensed healthcare services professional, and the **Payor**, referring to the public or private insurance company.

Note: the payor may also refer to the individual receiving healthcare services who pays out of pocket, and therefore, does not engage with an insurance company. In these cases, often referred to as "self-pay", the formal claims adjudication process is bypassed, and the patient settles the bill herself after services are rendered.

Depending upon many factors including the type of health care facility, type of services provided, and others, the following phases are often employed by healthcare service providers throughout a patient's health care journey:

1. Pre-Registration:
    a. **Patient**: The patient initiates contact with the healthcare facility to express the need for medical services. This may involve calling to schedule an appointment or utilizing online registration tools to provide initial information such as personal details, insurance information, and medical history.
    b. **Provider**: The healthcare facility may have online or telephone systems to facilitate pre-registration. They gather initial information to streamline the subsequent registration process and ensure the patient's details are prepared.
    c. **Payor**: the patient's insurance company is notified by the health care facility that a request for service has been made so that level of coverage and/or copay can be determined and communicated to the provider and patient, as needed.
2. Registration:
    a. **Patient**: Upon arriving at the healthcare facility, the patient is greeted by registration staff. They collect additional information, such as identification, insurance cards, and demographic details. The patient may be required to sign consent forms and provide any necessary co-payments or deductible payments.
    b. **Provider**: Registration staff collect and verify the patient's information, enter it into the facility's systems, and assign a unique identifier such as a medical record number. They may also verify insurance coverage, obtain necessary authorizations, and explain any relevant policies or procedures.
    c. **Payor**: The Claims Processing Department for the patient's insurance company begins claims adjudication by verifying the coverage and reimbursement owed to the service provider based on the patient's insurance plan.

3. Triage:
    a. **Patient**: In an emergency room or urgent care setting, patients undergo triage, where their condition's urgency is assessed. The patient provides information about their symptoms and medical history to the triage nurse or healthcare professional.
    b. **Provider**: A triage nurse or healthcare professional evaluates the patient's condition, assessing the severity and determining the appropriate level of care and prioritization.
4. Medical Examination:
    a. **Patient**: The patient is guided to an examination room or area where they are seen by a healthcare provider. They provide detailed information about their symptoms, medical history, and any relevant concerns.
    b. **Provider**: The healthcare provider, such as a physician, nurse practitioner, or physician assistant, conducts a comprehensive examination, reviews the patient's medical records, orders diagnostic tests if necessary, and formulates a diagnosis or treatment plan based on the findings.
5. Treatment:
    a. **Patient**: Following the examination, the patient may receive treatments such as medication administration, procedures, therapies, or surgical interventions. They are educated about the treatment plan, potential side effects, and expected outcomes. The patient is encouraged to actively participate in their care and ask questions.
    b. **Provider**: Healthcare professionals deliver the necessary treatments, monitor the patient's progress, adjust the treatment plan as needed, and ensure appropriate documentation of the care is produced and provided.
6. Discharge:
    a. **Patient**: When the patient's condition stabilizes, they may be discharged from the healthcare facility. The patient receives instructions regarding self-care, medication usage, follow-up appointments, and potential warning signs. Any necessary prescriptions or medical supplies are provided.
    b. **Provider**: Healthcare professionals provide detailed discharge instructions, communicate with the patient about ongoing care requirements, coordinate referrals to specialists or other healthcare providers, and ensure a smooth transition from the facility to the next phase of care.
7. Billing:
    a. Patient: After the healthcare services are provided, the patient may receive bills or statements detailing the services rendered. The patient is responsible for understanding their insurance coverage, paying deductibles, co-pays, or any portion not covered by insurance.
    b. **Provider**: The healthcare facility generates bills or claims based on the services provided and submits them to the appropriate payors, such as insurance companies or government programs. Coding and billing professionals ensure accurate documentation and adherence to billing regulations.
    c. **Payor**: The payor reviews the claims information received from the healthcare provider's billing department including aspects of the patient's medical record documentation, the assessments from the healthcare providers coding and abstracting

specialists, determines the coverage and reimbursement eligibility, and communicates the payment details to the healthcare facility. The payor may also send an Explanation of Benefits (EOB) to the patient, outlining the services covered and any financial responsibility. Ultimately, the payer reconciles the payment for services to the service provider based on the outcomes of the decision points in their analysis of the episode of care.

It's important to note that the specific steps and terminology used in the healthcare services delivery process may vary between healthcare facilities and different types of care settings.

Appendix B: Healthcare Organizational Functions

To understand the practical utility of this module to the healthcare industry, this appendix identifies likely organizational stakeholders and participants Involved in the delivery of health care services in different phases. While the terms used to refer to these roles may be different from organization to organization, this is a general synopsis based on the role function.

A typical hospital in the United States consists of various operational functions and departments that work together to provide comprehensive healthcare services. Here is a list of some common operational functions and departments found in hospitals:

Strategic Planning and Leadership:

- Chief Executive Officer (CEO)
- Chief Operating Officer (COO)
- Chief Medical Officer (CMO)
- Chief Nursing Officer (CNO)
- Chief Financial Officer (CFO)
- Human Resources
- Quality Improvement and Risk Management

Clinical Departments:

- Emergency Department
- Intensive Care Unit (ICU)
- Surgery Department/Operating Theatre
- Obstetrics and Gynecology Department
- Pediatrics Department
- Internal Medicine Department
- Radiology Department
- Pathology and Laboratory Medicine
- Anesthesiology Department

Nursing Services:

- Nurse Manager/Supervisor
- Registered Nurses (RNs)
- Licensed Practical Nurses (LPNs)
- Nursing Assistants
- Nurse Educators

Medical Staff Offices:

- Pharmacy Department
- Laboratory Services
- Radiology and Imaging Services
- Rehabilitation Services (Physical Therapy, Occupational Therapy, Speech Therapy)
- Nutrition and Dietary Services
- Respiratory Therapy
- Social Services

- Medical Records and Health Information Management

Ancillary Services:

- Admissions and Registration
- Billing and Coding
- Patient Financial Services
- Health Information Technology (HIT) and Informatics
- Facilities Management
- Environmental Services
- Security and Safety
- Patient Transport

Specialized Departments and Centers:

- Cardiology Department
- Oncology Department
- Neurology Department
- Orthopedic Department
- Geriatric Department
- Rehabilitation Center
- Mental Health and Psychiatry Department

Supportive Functions:

- Medical Ethics Committee
- Infection Control
- Patient Advocacy
- Volunteer Services
- Research and Clinical Trials
- Medical Library

Please note that the specific departments and functions within a hospital can vary depending on the size, type, and specialization of the facility. Some hospitals may have additional specialized departments or centers based on their services and patient population.

Appendix C: Healthcare Use Cases

Multiple workflows, processes, and procedures within the healthcare realm show the promise of additional security, transparency, information portability, and demonstration of data ownership where blockchain technology is leveraged. This list comprises examples of compelling use cases in healthcare based on community interest or solutions being built for these purposes in the real world, along with a general description of how blockchain could be applied.

Case Management

Case management encompasses the entire rehabilitation and recovery process. It deals with every aspect of the process and facilitates continuity of care to promote better health outcomes.

Blockchain can securely store and share patient case data across multiple stakeholders, including healthcare providers, insurance companies, and caregivers. It ensures data integrity, enhances care coordination, and provides a transparent and auditable record of case updates and interventions.

Care Management

Care Management focuses on the patient's actual care and helps them transition between treatments and stages of care effectively.

Blockchain enables secure and interoperable sharing of patient care plans, treatment protocols, and outcomes among care teams and the patients they serve. It fosters collaboration, reduces duplicate efforts, and supports seamless transitions of care between different providers.

Provider Credentialing

Provider Credentialing refers to the process of verifying and evaluating the qualifications, professional background, and legitimacy of healthcare providers, such as physicians, nurses, therapists, and other allied health professionals. The purpose of provider credentialing is to establish and maintain a reliable system for assessing the qualifications and competency of healthcare professionals.

Blockchain can maintain a decentralized and tamper-proof database of verified provider credentials, licenses, and certifications. This streamlines the credentialing process, reducing administrative burden and improving the accuracy of provider information.

Physician Referrals

The Physician Referrals process allows primary care providers (PCPs) to refer their patients to specialists or other healthcare professionals for further evaluation, treatment, or specialized care. It involves the systematic transfer of patient care from one physician to another, ensuring continuity and comprehensive medical attention.

Blockchain facilitates efficient and secure physician referrals by providing a decentralized network where referring providers can access real-time information about specialists' availability, expertise, and patient feedback.

Document Management

Solutions that use digital assets to manage the recording, storing, and transmission of documents associated with patients, providers, and medical activities. This includes physician entries, provider data, and patient-supplied information such as data from wearables, manual entry, and diagnostic equipment. The term “document” within the context of this definition refers to a digital document that contains health or health service information of any type.

Blockchain-based document management ensures the integrity and authenticity of medical records, consent forms, and other critical documents. It offers an immutable audit trail, protecting against unauthorized changes or falsifications.

Medical Device Supply Chain

The Medical Device Supply Chain refers to the network of activities, processes, and resources involved in the production, distribution, and delivery of medical devices from manufacturers to end-users, including healthcare facilities, clinics, and patients. It encompasses the entire lifecycle of a medical device, starting from the procurement of raw materials to the post-market support and disposal of the device.

Blockchain can track the entire lifecycle of medical devices, from manufacturing to distribution and usage. It helps prevent counterfeit devices, ensures product authenticity, and enhances recall management.

Pharmaceutical Supply Chain

The Pharmaceutical Supply Chain refers to the network of processes, activities, and resources involved in the production, distribution, and delivery of pharmaceutical products, including prescription drugs, over-the-counter medications, vaccines, and other related healthcare products. It encompasses the entire lifecycle of pharmaceutical products, from raw (or “base”) material procurement to distribution to patients through providers such as hospitals and pharmacies.

Similar to medical devices, blockchain ensures transparency and traceability in the pharmaceutical supply chain, reducing the risk of counterfeit drugs and streamlining the process of tracking drug shipments.

Patient Engagement

Patient Engagement refers to the active involvement of patients in their own care and decision-making processes. It emphasizes the partnership between healthcare providers and patients, recognizing that engaged patients are more likely to have positive health outcomes, improved adherence to treatment plans, and better overall satisfaction with their healthcare experience. Patient engagement aims to empower patients, enhance communication, and promote shared decision-making to achieve optimal health outcomes.

Blockchain can enable patients to control and share their health data securely. It allows patients to participate in decentralized health apps, earn tokens for sharing data, and be incentivized for engagement in their own healthcare.

Claims Adjudication

Claims Adjudication refers to the process (by insurance companies?)of reviewing and deciding on healthcare insurance claims submitted by healthcare providers, facilities, or patients. It involves

assessing the validity, accuracy, and appropriateness of the claim based on various factors, such as the patient's insurance coverage, the services provided, and the applicable contractual agreements or guidelines.

Blockchain can facilitate real-time claims processing and adjudication by automating validation and verification of claims data through the execution of smart contracts. It streamlines the payment process and reduces fraud, leading to faster and more accurate claims resolution.

Patient Consent Management

Patient Consent Management refers to the process of obtaining, documenting, and managing the informed consent of patients for various healthcare interventions, procedures, treatments, or participation in research studies. It involves ensuring that patients understand the relevant information about their care, including potential risks, benefits, alternatives, and their rights, and voluntarily provide their consent or refusal based on that understanding.

Blockchain offers a decentralized and auditable consent management system, allowing patients to manage their consent preferences for data sharing and research participation.

Clinical Trials

Clinical trials are research studies conducted in the field of healthcare to evaluate the safety, efficacy, and effectiveness of medical treatments, interventions, drugs, devices, or procedures on human participants. These trials are essential for advancing medical knowledge, developing new therapies, and improving patient care.

Blockchain can enhance transparency, data integrity, and participant privacy in clinical trials. Smart contracts can automate trial protocols, consent management, and data collection, ensuring compliance and reducing administrative burden.

Materials Management

Materials Management refers to the process of cataloging, ordering, organizing and tracking the inventory of equipment, disposable goods, tools, consumables and products used by an organization in the execution of health service delivery. The Materials Management process can tie into specific supply chain processes (pharmaceutical, medical devices) but it's primarily concerned with the inventory an organization keeps on hand along with its connection to budgeting, associated or impacted cost centers, purchase orders, and consumption.

Example: The Materials Management process could track the number of KN-95 masks and latex gloves a health organization has in inventory, along with usage trends to predict when the next order cycle should be, what departments use the resources most, or what those articles are used with most often (surgical gowns +, for instance).

Blockchain enhances supply chain management for medical materials, equipment, and consumables, ensuring authenticity and origin verification, especially for critical medical supplies.

Patient Financials

Patient Financials refers to processes and workflows associated with patient billing and patient refunds. The overarching process is commonly referred to as Revenue Cycle Management by many health organizations and can encompass chart coding and abstracting, aspects of claims adjudication, payment processing, and collections.

Blockchain can streamline billing and payment processes, ensuring transparent and tamper-proof financial records. It allows patients to track and manage their healthcare expenses more effectively.

Health Information Exchanges (HIEs)

A Health Information Exchange (HIE) is a secure and interoperable electronic system that allows the sharing of healthcare-related information among different healthcare organizations, such as hospitals, clinics, laboratories, research facilities, pharmacies, and other healthcare providers. The primary goal of an HIE is to facilitate the exchange of patient health information in a standardized format to improve the delivery of healthcare services. This data exchange between organizations can be used for public health reporting, clinical decision support, peer reviews, care coordination between facilities, and the like.

Note: A secure and successful HIE requires a focus on interoperability between connected systems regardless of the vendor or the technology used by each organizational participant. HIEs typically incorporate a robust Consent Management protocol and Identity Management strategy.

Blockchain-based health information exchange ensures secure, interoperable, and consent-driven data sharing between healthcare entities while maintaining patient privacy and data integrity.

Overall, blockchain technology can revolutionize various aspects of healthcare by promoting data security, interoperability, transparency, and patient-centricity. However, widespread adoption requires careful consideration of regulatory compliance, standardization, and integration with existing healthcare systems.

Appendix D: Solution Transaction Modality / Healthcare Requirements Matrix

Solution Transaction Modality / Requirements	Patient Facing Systems	Auditing & Internal Systems	Cohort Systems	Reporting Systems
3rd Party ID Validation				
Auditing and Reporting				
Credential Management				
Delegated Authority				
Intermediary Provision				
RBAC[5]				
Data Migration				
Interoperability				
HIPAA[7] Compliant				
GDPR[8] Compliant				
Selective Disclosure				
HL7[9]/FHIR[10] Capable				
KYP[11]				
ISO 13485[12]				
Handles PHI[13]				
Handles X12[14]				

Legend: **R** = Required **A** = needs Assessment to decide Applicability **O** = Optional **N** = Not Applicable

The chart above can be used as a tool to outline each **Solution Transaction Modality** as well as the organizational or technical **Requirements** in scope for an assessment.

This defines how the proposed solution interacts with stakeholders and participants, and thus, determines how the data is transacted upon.

The relevance of the requirements for the solution's implementation are solution-specific, are categorized as **R** = **Required, A** = **needs Assessment to decide Applicability**, **O** = **Optional**, and **N** = **Not Applicable**, and are decided upon in the initial discovery phase of the assessment.

Any change to the status of the requirement can be agreed upon between the lead assessor, the solution provider, and/or the organization seeking to implement the blockchain solution.

This matrix is used to define the scope for assessments of blockchain solutions irrespective of use case. Requirements may also be added depending on an organization's need, policies, processes or governance.

Appendix E: Acknowledgements

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