Use Case Summary

NAME OF UC:

EXCHANGE CONSUMER[1] CONSENT INFORMATION

Sponsor(s): MDHHS / MiHIN

Date: December 15, 2015

The purpose of this Use Case Summary is to allow Sponsors, Participants, and other readers to understand the purpose of the Use Case (UC), the value proposition the UC represents, and what the Use Case does, requires, and how the UC operates at a high level. The summary is intended to assist the HIE and HIT Community understand where this UC fits within the overall roadmap for statewide sharing of health information.

This UC Summary has several sections allowing readers to understand the impact of this UC in the following areas: health outcomes, regulation, cost and revenue, implementation challenges, vendor community, and support.

Executive Summary

In this section provide a brief (3-5 sentence) summary of the UC's function and purpose. Also include a brief description of the importance and highlight the expected positive impact from implementation of this UC.

State and federal laws offer privacy protection for individuals and their health information. Certain types of health information, such as behavioral health and substance use disorder information, require different degrees of protection than physical health information. For example, state and federal laws require healthcare providers to obtain written consent from a consumer before behavioral health or substance use disorder information may be disclosed to another person or organization.

Although laws require a consumer's written consent to disclose behavioral health or substance use disorder information, there has been no standard written form for consumers to provide consent. This lack of standardization has led to confusion and conflicting consent forms and has become a barrier to information sharing and care coordination.

Some states, including Michigan, have attempted to address these problems by passing legislation that calls for the creation of a standard consent form that will be accepted and honored on a statewide basis. Michigan has also worked towards identifying a statewide solution for submission, discovery, and revocation of consumer consents. There is also a need for a standard statewide method for consumer consent information to be electronically stored, managed, queried, or deleted when expired.

The Exchange Consumer Consent Information Use Case addresses the statewide need for a standard, shared way to manage consumer consent forms and consent-related information in a Health Information

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[1] In this document, consumer refers to individuals receiving services related to behavioral health and/or substance abuse issues

Exchange environment. This Use Case helps organizations determine what information, if any, a consumer has consented to share and with which providers the information may be shared.

The Exchange Consumer Consent Information Use Case enables a standard, statewide service through which consumer consent can be (a) submitted, (b) revoked, or (c) requested, so that healthcare providers can quickly determine whether they can share health information that falls into one of the protected categories. This Use Case also enables better privacy and protection for consumer health information, while facilitating electronic sharing between providers in cases where the consumer has consented.

For the purposes of this Use Case, mental health and substance use disorder records are referred to as "behavioral health information." Behavioral health information should be distinguished from "physical health information," which is generally shareable by providers *without* consumer consent for the purposes of Treatment, Payment, and Operations (TPO) under the federal Health Insurance Portability and Accountability Act (HIPAA).

Historically the behavioral health community has been limited in its ability to participate in electronic health information exchange because the disclosure of behavioral health information requires more specific consumer consent than is required under HIPAA as mandated by 42 CFR Part 2 and the Michigan Mental Health Code.

According to the report "An Electronic Consent Management Architecture to Support Behavioral Health Information Exchange in Michigan" by the CIO Forum Data Exchange Workgroup (a leadership forum for Chief Information Officers (CIOs) from Community Mental Health Service Providers and Pre-paid Inpatient Health Plans), two components must be in place for the behavioral health community to participate fully in health information exchange:

1. A standard, statewide behavioral health consent form for care coordination purposes. Such a form, accepted by all parties, would allow consumer consent to be collected wherever the consumer is present and shipped electronically to providers and Health Information Exchanges (HIEs) that need this consent to release information.[2] A standard form facilitates care coordination and supports integration of physical and behavioral healthcare.
2. Description, specifications and implementation of an Electronic Consent Management System (eCMS).[3] For an HIE to efficiently and effectively handle behavioral health consent, it needs to be consistent with the consent methodologies of other HIEs. This allows interoperability.

The approach recommended by the CIO Forum allows the behavioral health community to transition from a paper- and fax-based system of communicating consumer privacy and consent preferences to an electronic system that supports data sharing (including Continuity of Care Documents) while maintaining compliance with federal and state laws, including 42 CFR Part 2 and the Michigan Mental Health Code, respectively.

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[2] On January 1, 2015, the Michigan Department of Community Health released a standard consent form for the sharing of health information specific to behavioral health and substance use treatment information in accordance with Public Act 129 of 2014.

[3] An eCMS (electronic Consent Management System) is a repository that stores original consent data and documents and may be associated with one or more Health Information Exchanges (HIEs) and/or healthcare organizations.

The Exchange Consumer Consent Information Use Case includes the CIO Forum's recommendations and reflects the eCMS architecture (discussed more fully in the Use Case Implementation Guide).

Diagram

In this section, provide a diagram of the information flow for this UC. The diagram should include the major senders and receivers involved and types of information being shared.

Between November 2014 and January 2015, MDHHS tasked MiHIN with facilitating a Consent Use Case Working Group to determine the primary Use Cases surrounding Michigan's standard consent. The Working Group eventually agreed upon this single initial Use Case, to include three data sharing scenarios: (a) Submit consent, (b) Revoke consent, and (c) Request consent.

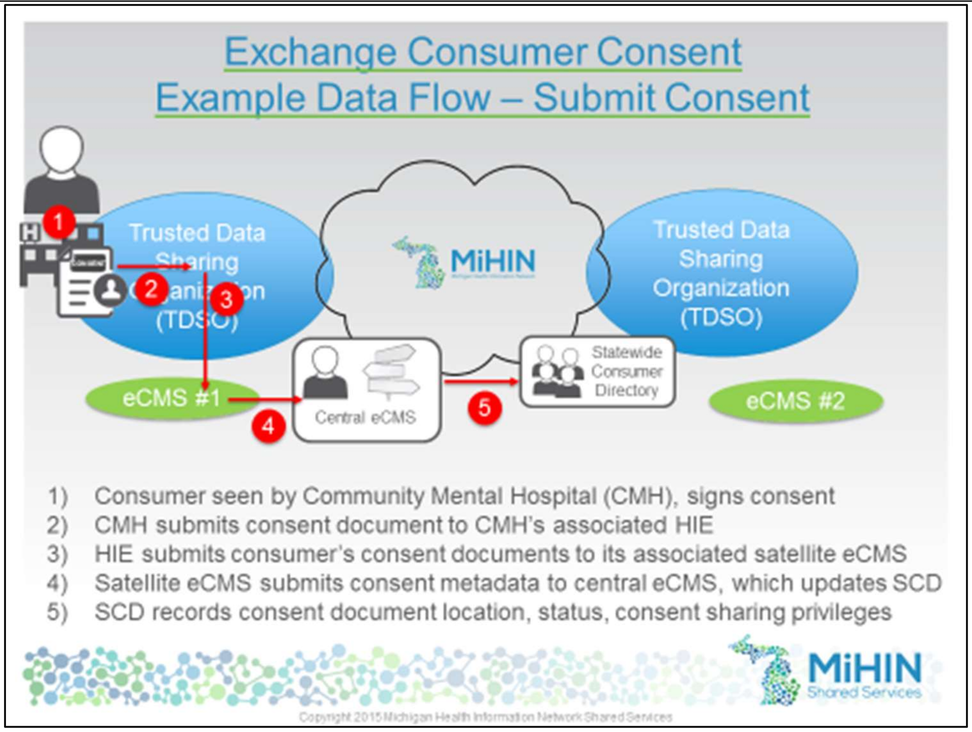
To implement the information flow for these three data sharing scenarios, this Use Case utilizes the Statewide Consumer Directory (SCD) developed by MDHHS and MiHIN as well as one or more eCMS repositories containing actual consumer consents that are connected to Health Information Exchanges (HIEs). Because there are multiple HIEs in Michigan, there can be more than one eCMS – the Statewide Consumer Directory helps coordinate between the eCMS repositories so that consent can be managed or queried on a statewide basis.

The Statewide Consumer Directory (SCD) is a service that helps consumers manage their healthcare information, their preferences, and the ability to make sure their correct information is available to the healthcare providers of their choice when needed. The SCD records the location of other consumer consents, such as consent to clinical trial, and also points to consumer preferences such as Advance Directives. A short video summary of the Statewide Consumer Directory is available at:

http://www.mihin.org/2015/12/14/scd/

The following is an example flow of the first data sharing scenario in this Use Case, submit consumer consent:

1) A consumer is seen by the local Community Mental Health facility (CMH). To better manage her coordination of care, she signs a consent form to allow her behavioral health information to be shared with her primary care physician, her Medicaid Health Plan, and her CMH;
2) The CMH submits the consumer's consent document to the CMH's associated HIE;
3) The HIE submits the consumer's consent documents to its associated "satellite" eCMS;
4) The satellite eCMS submits the consent metadata to the shared eCMS, which then updates the SCD;
5) SCD records the consent document location, status, and consent sharing privileges.



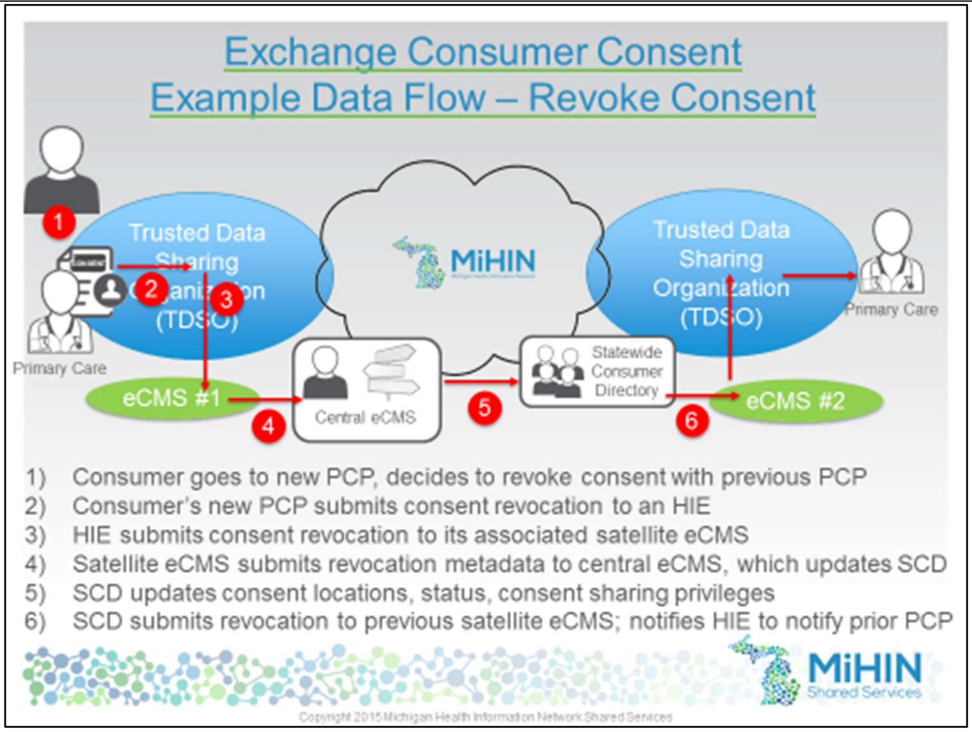
Exchange Consumer Consent
Example Data Flow – Submit Consent

1) Consumer seen by Community Mental Hospital (CMH), signs consent
2) CMH submits consent document to CMH's associated HIE
3) HIE submits consumer's consent documents to its associated satellite eCMS
4) Satellite eCMS submits consent metadata to central eCMS, which updates SCD
5) SCD records consent document location, status, consent sharing privileges

Under this scenario, the satellite eCMS can register the consent with the SCD – simply notifying SCD that a consent exists between two parties for a certain period. The satellite eCMS provides metadata about the consent form to the shared eCMS for storage, but does not share the actual consent form.

A second data sharing scenario under this Use Case allows the satellite eCMS to send a revocation of consent as shown in the example below:

1) A consumer is seen by a new PCP and decides to revoke the consent with her previous PCP;
2) The consumer's new PCP submits her consent revocation to an HIE;
3) The HIE submits consent revocation to its associated satellite eCMS;
4) The satellite eCMS submits the consent revocation metadata to the shared eCMS, which then updates the SCD;
5) SCD updates consent locations, status, and consent sharing privileges;
6) SCD submits revocation to consumer's previous associated satellite eCMS location based on information in SCD; notifies HIE to notify prior PCP.



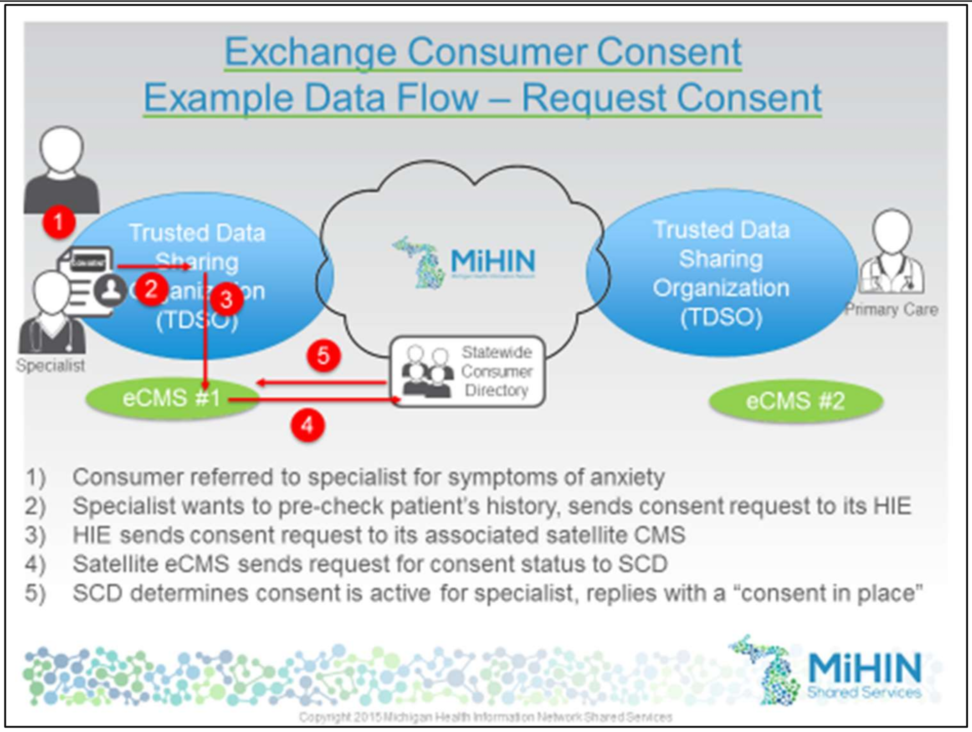
Exchange Consumer Consent Example Data Flow – Revoke Consent

1) Consumer goes to new PCP, decides to revoke consent with previous PCP
2) Consumer's new PCP submits consent revocation to an HIE
3) HIE submits consent revocation to its associated satellite eCMS
4) Satellite eCMS submits revocation metadata to central eCMS, which updates SCD
5) SCD updates consent locations, status, consent sharing privileges
6) SCD submits revocation to previous satellite eCMS; notifies HIE to notify prior PCP

Due to the wide variety of possible combinations of providers, consumers, HIEs and eCMS solutions, a satellite eCMS will always be required to check with the SCD to determine if a consent is still in effect, in case it has been revoked through a separate eCMS.

Finally, the Use Case allows request for consent status as follows:

1) A consumer is referred to a specialist for symptoms of anxiety;
2) The specialist wants to pre-check the consumer's healthcare history and sends a consent request to its associated HIE;
3) The HIE sends consent request to its associated satellite CMS;
4) The satellite eCMS sends a request for consent status to the SCD;
5) SCD determines consent is active for the specialist and replies with a "consent in place" message;
6) This message is returned to the consumer's specialist so that the specialist's healthcare information request can be made and fulfilled (using another Use Case such as Request Patient Information, formerly called "Cross QO Query");
7) The specialist now has the consumer's full healthcare history for their appointment.



Exchange Consumer Consent Example Data Flow – Request Consent

1) Consumer referred to specialist for symptoms of anxiety
2) Specialist wants to pre-check patient's history, sends consent request to its HIE
3) HIE sends consent request to its associated satellite CMS
4) Satellite eCMS sends request for consent status to SCD
5) SCD determines consent is active for specialist, replies with a "consent in place"

MiHIN Shared Services

Please note: SCD will only return a value of 'consent in place for named recipient' or 'consent not in place for named recipient.' It will not disclose if a prior consent has expired or been revoked.

Regulation

In this section, describe whether this UC is being developed in response to a federal regulation, state legislation or state level administrative rule or directive. Please reference the precise regulation, legislation, or administrative act such as Public Law 111-152 (Affordable Care Act), Public Law 111-5; Section 4104 (Meaningful Use), 42 CFR 2 (substance information), MCL § 333.5431 (Newborn Screening), PA 129 (standard consent form), etc.

Additionally, provide information if this UC will allow Eligible Professionals/Providers (EP) or Eligible Hospitals (EH) to meet an attestation requirement for Meaningful Use.

Legislation/Administrative Rule/Directive:

☒ Yes
☐ No
☐ Unknown

Name or number of legislation, rule, directive, or public act:

Federal Laws or Regulations:

Health Insurance Portability and Accountability Act of 1996 (HIPAA)
42 CFR Part 2 (Code of Federal Regulations)
Violence Against Women Act
Family Violence Prevention and Services Act

Federal Guidance:
“Applying the Substance Abuse Confidentiality Regulations 42 C.F.R. Part 2 (Revised)” (2011)
http://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs

Michigan laws:

Michigan Mental Health Code: Public Act 258 of 1974, MCL 330.1001 *et. seq.*

Michigan Public Act 129 OF 2014 - establishes statewide standard consent form for those involved in treatment

Summary:

Multiple state and federal laws govern confidentiality of health information limiting how healthcare providers, payers and others can share health information.

The Health Insurance Portability and Accountability Act (HIPAA) establishes a minimum of safeguards for protected health information. This federal law applies no matter how health information is shared, whether electronically, in writing, or verbally. In general, HIPAA allows protected health information to be shared for the purposes of “treatment, payment, and health care operations (TPO).” By signing a Notice of Privacy Practices acknowledgement with a healthcare provider or health system, a consumer is effectively acknowledging they understand that providers can share their physical health information among other providers and payers for TPO purposes as specified under HIPAA.

Other health information is much more restricted by state and federal law. 42 CFR Part 2 requires consumer consent for the disclosure and use of consumer records for alcohol and drug use, which are maintained in connection with the performance of any federally assisted alcohol and drug abuse program. The Michigan Mental Health Code (MCL 330.1748) also requires consent prior to the disclosure of a recipient’s mental health records. For 42 CFR Part 2 and the Michigan Mental Health Code, providers must obtain consent to share mental health and substance use disorder records, unless the disclosure falls within one of the enumerated exemptions to consent, such as a medical emergency (“break the glass”).

In accordance with Public Act 129 of 2014, the Michigan Department of Health and Human Services released a statewide standard consent form on January 1, 2015. Michigan’s standard consent form is designed to meet the requirements of 42 CFR Part 2 and Michigan’s Mental Health Code for care coordination purposes. **This Use Case is focused on the electronic management and exchange of consumer consent information statewide.**

Meaningful Use:
☒ Yes
☐ No
☐ Unknown

This Use Case does not singularly meet any requirements of Meaningful Use; however this Use Case may help facilitate exchange of information, which can assist in meeting Meaningful Use requirements.

Cost and Revenue

In this section provide an estimate of the investment of time and money needed or currently secured for this UC. Be sure to address items such as payer incentives, provide incentives, revenues generated (e.g. SSA transaction payments) or cost savings that could be realized (i.e. reduction of administrative burden).

As information is known or available, provide information on the resources and infrastructure needed to move this UC into production.

Costs: There are two costs associated with this Use Case. First, the cost of implementing this Use Case, which requires use of new and existing infrastructure and is estimated to be in the high six figures. New infrastructure required for this Use Case includes deploying a shared electronic Consent Management System (eCMS) that records "metadata" from all other eCMS instances statewide, the cost for which is still being determined. Additionally, this shared eCMS must be integrated with the Statewide Consumer Directory (SCD). The cost for integration and testing with the SCD is included in the high six figure estimate for this Use Case.

The other potential cost for this Use Case is that of not implementing it. This cost is estimated to be millions of dollars in annual waste due to difficulties and delays storing, managing, coordinating and communicating behavioral health information, as well as potential damages from improperly communicated consumer information. Implementing this Use Case can also reduce the annual costs of maintaining and supporting multiple disconnected repositories of consumer consent forms, which is estimated to be millions of dollars per year. Further, implementing this Use Case will accelerate adoption of a statewide standard consent form (both paper and electronic) which also leads to immense cost reductions, particularly in areas such as diversions and related legal and judicial costs.

The Return On Investment (ROI) for successfully implementing and adopting this Use Case is good – a high six-figure investment for a potential high nine-figure return.

Revenues: The cost savings and workflow efficiencies achieved by enabling healthcare providers to more easily store, manage, locate and access consumer consent information should prompt stakeholders to subscribe to this service. MiHIN is preparing a pricing model for subscriptions to sustain this service. The pricing model will likely vary by participating organization, and may be similar to a data plan offered by a wireless carrier. This could include a base fee for a certain number of data-sharing transactions with additional per-transaction fees for notifications beyond that baseline on a monthly basis. Storage of consumer consent information (meta-data) may also be offered as a fee-based service.

Stakeholders who may wish to participate in the electronic exchange of consumer consent forms include but are not limited to:

- Providers
- Prepaid Inpatient Health Plans
- Community Mental Health Agencies
- Hospitals
- Specialists
- Home Health Care / LTPAC / Skilled Nursing Facilities
- Rehabilitation Centers
- Payers
- Pharmacies
- Health Plans / Payers

- Accountable care organizations or health homes.

This section will be updated when the full revenue model for this Use Case is finalized.

Implementation Challenges

In this section, as information is known or available, describe challenges that may be faced to implement this UC. Be sure to address whether the UC leverages existing infrastructure, policies and procedures, ease of technical implementation, or impacts current workflows (short term and long term).

While much of this Use Case utilizes existing MiHIN infrastructure, the establishment of a shared eCMS that coordinates other eCMS instances is new infrastructure and will necessitate spending time and effort to properly scope project requirements, to find the right vendor for the project, and to implement an eCMS that is integrated with the rest of MiHIN's existing infrastructure. Implementation costs for this shared "metadata" eCMS are not fully defined and will need to be modified to accommodate vendor pricing and capabilities of the selected eCMS.

Other challenges include encouraging Trusted Data Sharing Organizations to prioritize this Use Case to ensure they properly connect to the shared eCMS and to satellite eCMS solutions to receive and respond to requests for consent; educating healthcare providers on the new solution and encouraging them to use it; and helping to define new workflows to support the electronic exchange of consumer consent information.

Vendor Community Preparedness

In this section, address the vendor community preparedness to readily participate in the implementation of this UC. Speak to whether this UC will utilize current or future technical capabilities of the vendor products. If this UC requires new functionality at the vendor level provide information as known to the timeliness of when product updates may be available and any potential costs to the HIE community.

One of Michigan's behavioral health technology vendors and at least one of Michigan's Health Information Exchanges have implemented electronic consent management functionality that is in production, using an electronic version of the standard behavioral health consent form. These organizations are in the process of updating and modifying to align with the latest eCMS specification ("An Electronic Consent Management Architecture to Support Behavioral Health Information Exchange in Michigan" by the CIO Forum Data Exchange Workgroup) and have expressed interest in utilizing a shared eCMS solution to support customers statewide. Fortunately, the eCMS specification is modeled after the "Query By Parameter (QBP)" specification standardized by the Centers for Disease Control (CDC) for use in querying an Immunization Information Systems (IIS) such as the Michigan Care Improvement Registry (MCIR) for Immunization History/Forecast. Since Immunization History/Forecast is anticipated to be a high-demand Use Case, organizations building or buying their own eCMS are likely to implement the QBP specification that Immunization History/Forecast and eCMS share in common.

Other behavioral health solution vendors serving Michigan have conveyed intentions to participate in a statewide solution to improve data sharing needs of the behavioral health community while adhering to state and federal regulations and the eCMS specification.

Prepaid Inpatient Health Plans (PIHPs) are dependent on their vendors' participation (e.g. PCE Systems, Streamline, NetSmart).

Some Trusted Data Sharing Organizations including Qualified Organizations (QOs) such as Washtenaw County Community Support and Treatment services have deployed eCMS solutions for their customers to enable sharing behavioral health information.

Other QOs like Northern Physicians Organization (NPO), a HIE-QO, have developed their own consent and behavioral health information sharing solutions. There may be challenges to determining how the Exchange Consumer Consent Information Use Case can complement and augment these existing solutions, and whether existing solutions can conform to the eCMS protocol specification.

The transport of consent information may not be included as base functionality for some Electronic Health Record/Personal Health Record vendors; however, if it is not current functionality, it is likely to be on their future road map due to the above reasons

Support Information

In this section, provide known information on the support for this UC.

Support can come from multiple levels (Governor, Federal or State Legislative, MI HIT Commission, Michigan State Departments, CMS/ONC/CDC, MiHIN Board, Qualified Organizations, Payer Community, Interest Group [ex: MSMS, MHA], or Citizen support).

Please note any concerns or oppositions with the Use Case.

Political Support:
☒Governor
☒Michigan Legislature
☒HIT Commission
☒MDCH or other SOM Department
☐CMS/ONC
☐CDC
☒MiHIN Board
Other:

Concerns/Oppositions: There are general concerns about implementing behavioral health information sharing in accordance with SAMHSA and 42 CFR Part 2. Specific concerns have been raised about whether each HIE, HIN, or other HIO in a network must be named as a "recipient" by a patient giving consent based on an FAQ published by SAMHSA (see FAQ link in **Regulation** section of this document).

Sponsor(s) of Use Case

Who are the major sponsors of the use case?

Michigan Department of Health and Human Services (MDHHS)
Michigan Health Information Network Shared Services (MiHIN)

Metrics of Use Case

In this section, define metrics for the Use Case to be successful.

Connecting one (1) or more Trusted Data Sharing Organization(s), each with a satellite eCMS, to the shared eCMS and Statewide Consumer Directory so that consent forms can be loaded (submitted), located, revoked and queried from another Trusted Data Sharing Organization.

Metrics to measure the success of the Use Case include:

- Number of Trusted Data Sharing Organizations connected with a satellite eCMS to shared eCMS and Statewide Consumer Directory
- Number of providers using Exchange Patient Consent Information Use Case
- Number of consent “metadata” records submitted to shared eCMS
- Number of consent “metadata” records queried by providers through shared eCMS

Other Information

This section is to afford the sponsor(s) an opportunity to address any additional information with regard to this UC that may be pertinent to assessing its potential impact.

Consent for minors

Some of the statutory and regulatory requirements that govern privacy and consent for the sharing of health information for minors differ from the consent requirements for adults. The unique privacy and consent requirements for minors fall into 2 categories: (1) designation of the age that a minor may consent to disclose health information; and (2) restrictions and regulations on when a parent may access health information on a minor who has reached adulthood and/or the age of consent. These regulations and restrictions must be addressed in the Exchange Consumer Consent Information Use Case before sensitive health information for minors can be shared electronically.

The requirements for handling consent for minors are not yet fully reflected in this Use Case Summary and must still be developed.