Use Case Summary

<table>
<thead>
<tr>
<th>Use Case Name:</th>
<th>Organ Donor Notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor:</td>
<td>Gift of Life Michigan and Michigan Health Information Network Shared Services</td>
</tr>
<tr>
<td>Date:</td>
<td>August 18, 2016</td>
</tr>
</tbody>
</table>

Executive Summary

This brief section highlights the purpose for and value of the use case. The executive summary gives a brief description of the use case's importance while highlighting expected positive impact.

According to Gift of Life Michigan, every month about 3,000 patients die in Michigan hospitals. Regulations from the Centers for Medicare and Medicaid (CMS) require all of those deaths to be reported to the federally-designated organ procurement organization (OPO) for the region in which the hospital is located. In Michigan, the federally-designated OPO is Gift of Life Michigan.

This report to an OPO is known as a “routine notification” and is required to be made within one hour of death. In addition to routine notification calls made after death has occurred, hospitals are required to call the OPO whenever there is a still-living patient presented with life-threatening injuries or their clinical condition deteriorates to the point that it activates predefined clinical triggers (e.g. presence of a neurological injury and/or the patient is on a ventilator). Because a patient’s condition can fluctuate, multiple notification calls may be necessary as the patient’s condition changes.

The notification is intended to ensure that the OPO is made aware of deaths in a timely fashion, so all deceased patients suitable for organ or tissue donation have the opportunity to donate. These deceased patients represent the pool of candidates potentially eligible for tissue donation.

Purpose of Use Case: The purpose of the Organ Donor Notifications use case is to provide a method of electronic notification of hospital deaths to a federally-designated OPO as required by federal and state regulations.
Overview

This overview goes into more details about the use case.

The traditional method for communicating a routine notification is for a member of the hospital staff (frequently a nurse) to make a phone call to the OPO. During this call, the staff member relays a small set of facts to the OPO about the decedent or a patient who meets the clinical triggers for a possible donation. In the majority of cases, a review of the clinical circumstance and social history results in the determination that there is no donation potential and the call is complete. However, if there is donation potential, the phone call is extended and the staff member is asked to provide additional clinical and social data to the OPO.

Making this phone call may be viewed as a burden for the hospital staff because:

- It takes time away from other duties, especially when the unit is busy. When there is the potential for an organ donation, this may require multiple calls seeking information and clarification regarding the potential donor.
- Routine notification phone calls typically are unfamiliar to hospital staff members, because any individual staff member may encounter this type of situation only a few times a year.
- Answering the questions regarding the donor often requires searching through multiple sections of the electronic health record, which extends the length of time required from hospital staff.
- Verbally reporting the information to the OPO for transcription creates the opportunity for communication and/or transcription errors to occur.

The Organ Donor Notifications use case encompasses the transfer of specific data points on any deceased or near-death patient to an OPO via the statewide health information network (HIN). Because this is done electronically, no phone call is required. Therefore, this use case allows hospital staff to focus more time on their other duties.

Also, since the data is transferred directly, the desired information is available to the OPO in an accurate and timely manner; communication and transcription errors are reduced or eliminated. Hospitals can better meet the CMS routine notification requirements for both completeness (no missed referrals) and timeliness (notification within one hour). This is all accomplished with less of a burden on hospital resources, as well as allows improved outcomes for tissue and organ recipients.

Finally, in the event that the electronic notification results in a determination that there is donation potential, the OPO staff will contact the hospital directly to pursue the donation.
Diagram

This diagram shows the information flow for this use case.

![Diagram](image.png)

**Figure 1. Path for Organ Donor Notifications**

**Note:** The diagram implies that the notification data may be sent through a health information exchange or other trusted data-sharing organization that is connected to HIN.

Regulation

This section describes whether this use case is being developed in response to a federal regulation, state legislation or state level administrative rule or directive.

**Legislation/Administrative Rule/Directive:**

- Yes
- No
- Unknown

- Public Law 111-152 (Affordable Care Act)
- Public Law 111-5; Section 4104 ( Meaningful Use)
- 42 CFR Parts 413, 441, et al. Medicare and Medicaid Programs; Conditions for Coverage for Organ
- Procurement Organizations (OPOs); Final Rule
- 42 CFR Parts 482.45 Medicare and Medicaid Programs; Hospitals: Condition of Participation: Organ, Tissue, and Eye Procurement
- 21 CFR Parts 1270 and 1271 U.S. Food and Drug Administration: Human Cells, Tissues, and Cellular and Tissue-Based Products
Cost and Revenue

This section provides an estimate of the investment of time and money needed or currently secured for this use case.

Costs: This use case includes the following cost components:

- Development of message protocols compatible with certified EHR systems to submit and receive routine notifications
- HIE-QO (Health Information Exchange-Qualified Organization) development and implementation to onboard for this use case (optional)
- Hospital/health system implementation and integration
- Pilot and testing costs for transmission of routine notifications from hospitals to OPO (costs will vary per organization)

Revenue: Revenue for this use case will primarily consist of cost savings from process efficiencies. Overall, it is anticipated there will be cost savings equivalent to hospital and OPO staff time saved by not communicating the notification by phone. Per Gift of Life Michigan, roughly five minutes are spent on each notification from a hospital. This equates to 3,000 x 5 minutes, or 15,000 hospital staff minutes per month saved for routine death notifications alone (an estimated annual time savings of approximately one-and-a-half full-time employees). Equivalent time is required for OPO staff as well.

This estimate does not include the times a nurse must re-contact the OPO due to missing data points, inability to complete the call due to hospital emergencies, etc. Additional cost savings are realized because:

- Many of the follow-up calls that are required on any potential organ and/or tissue donor will be avoided
- Transcription and communication errors will be avoided
- Full compliance with regulatory reporting requirements is automatically achieved
Implementation Challenges

This section describes the challenges that may be faced to implement this use case.

Implementation challenges are anticipated to be limited to the usual constraints of programming resource availability.

Implementing the Organ Donor Notification use case will require software development on the part of the hospital EHR team. In particular, the following items will be required:

- A set of triggers within the EHR to notice when a particular patient’s record indicates that they have died or are near death
- A search to gather the desired data points from the EHR
- Code to transfer the data from the EHR to HIN
- Code to accept the confirmation status from HIN and mark the case as having been notified

Vendor Community Preparedness

This section addresses the vendor community preparedness to readily participate in the implementation of this use case.

Gift of Life Michigan has designed and implemented a similar program for medical examiners (MDILog). Currently, approximately one-half of Michigan medical examiners are making referrals via this electronic notification system. With the application’s feasibility already tested and currently running, it is believed that this can be applied readily to hospital routine notifications.

Support Information

This section provides known information on this support for this use case.

Support can come from multiple levels (Governor, Federal or State Legislature, Michigan HIT Commission, Michigan State Departments, CMS/ONC/CDC, MiHIN Board, Participating Organizations, payer community, interest groups [e.g. MSMS, MHA], or citizen support).

Political Support:

☒ Governor
☒ Michigan Legislature
☐ Health Information Technology Commission
☐ Michigan Department of Health and Human Services or other State of Michigan department
☐ CMS/ONC
☐ CDC
☐ MiHIN Board

Other: None Noted.

Concerns/Oppositions: None noted.

Sponsor(s) of Use Case

This section lists the sponsor(s) of the use case.

- Gift of Life Michigan
- Michigan Health Information Network Shared Services
- Bronson Medical Center
- Upper Peninsula Health Information Exchange (UPHIE)

Metrics of Use Case

This section defines the target metrics identified to track the success of the use case.

The key metrics for this use case include:

- Routine notifications arrive at OPO within one hour of time of death or time when clinical triggers were met
- Data set is sufficient to determine donation potential
- Required notifications are not missed
- Notifications are not duplicated
- Notification-related call volume is reduced by 75%

Other metrics may be identified.
Other Information

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

Data items for the routine notification required from the hospital’s EHR:

**Basic Data:**
1. Phone # to unit
2. Hospital name
3. Unit
4. Name and title of hospital caller
5. Is the patient on a ventilator? (“Yes,” “Previously,” or “Never”)
   • If previously: date and time of extubating
6. Patient name
7. Date of birth
8. Race, sex, weight
9. Medical record number
10. Date and time of death
11. Date and time of admit
12. Cause of death

**Follow-Up Data for Cases that Do Not Meet Immediate Rule Out Criteria:**

- Volume of crystalloids/normal saline received in last hour prior to death
- Any blood products received in past 48 hours
  
  These are imperative and without this info the OPO cannot proceed with the case. If it appears the patient is plasma diluted, OPO will need to contact the blood bank or other departments to determine if a pre-transfused sample of blood is available.

- Admission course and circumstances of the death
- Any signs of infection or sepsis
- Any positive blood or sputum cultures
- Last three white blood cell counts
- Last three temperature readings
- Chest X-rays
- Decubitus ulcers and stage of ulcer
- Any high-risk behavior, if known (for example: jail, drug abuse/intravenous drug abuse, and track marks)
- Any infectious disease consults
- Surgical procedures with explanation
- Trauma, open or closed fractures, abrasions, road rash
- Any known current or past medical history, with emphasis on cancer, dementia, Alzheimer’s, Hepatitis, HIV
- Medical examiner case, police involvement
- Next of kin name, number, and relationship
- Next of kin prepared to speak with OPO
- Funeral home name, if possible a location and/or phone number
- Time body was placed in the morgue cooler

**For Emergency Room/Emergency Department Deaths:**
- Was this a witnessed event?
  - Who witnessed it?
- Did Emergency Medical Services (EMS) respond?
  - Did they start cardiopulmonary resuscitation (CPR)?
  - Give advanced cardiovascular life support (ACLS)?
  - Intubate
  - Shock
- Was code continued in Emergency Room?
- Did patient have a rhythm for EMS or in ER – even a fine v-fib or pulseless electrical activity (PEA)?
- Was there any blood loss?

**The Following Questions Are Required by Tissue Banks:**
- Do records or other information indicate the potential donor has ever tested positive for HIV, HBV, or HCV or significant infectious relevant communicable disease agents and diseases (RCDADs)?
- Do records or other information indicate the potential donor has had clinical evidence of signs or symptoms of hepatitis B or C?
  - Signs and symptoms include yellow jaundice, or hepatomegaly (records of laboratory data such as ALT, AST, bilirubin, or prothrombin time may assist in making a donor suitability determination)
- Do records or other information indicate the potential donor had close contact with individuals having viral hepatitis within the past 12 months?
- Do records or other information indicate the potential donor has ever had any clinical signs or symptoms of HIV infection or AIDS, as listed below?
  - **Signs and symptoms include:** Unexplained persistent white spots or unusual blemishes in the mouth; unexplained weight loss; blue or purple spots on the skin or mucous membranes typical of Kaposi’s Sarcoma; unexplained lymphadenopathy of longer than one month; unexplained temperature of over 100.5 degrees F (38.6 C); shortness of breath; opportunistic infections; or unexplained persistent diarrhea.
- Do records or other information indicate the potential donor has ever received medications listed below for AIDS, hepatitis, or related infections?
  - **Medications include:** AZT, retrovir, ddi, didanosine, Videx, ddC, zalcitabine, Hiben, DF4T, stavudine, Zerit, 3TC, lamivudine, Bactrim DS, trimethoprim and sulfamethoxasome combination (prescribed in a preventative dose of one tablet per day or one tablet three times a week), dapsone, interferon, oral Chlotrimazole, pentamidine, rifabutin or Mycobutin or any other medications associated with treating AIDS or hepatitis.
Do records or other information indicate the potential donor engaged in any activities considered high risk for HIV or hepatitis B or C infection as listed below?

- **High risk activities include:** Men who have had sex with another man within the preceding five years, persons who have injected drugs for a non-medical reason in the preceding five years (including intravenous, intramuscular or subcutaneous injections of recreational or illegal drugs), persons with hemophilia or related-clotting disorders who have received clotting factor concentrates, or persons who have had sex in exchange for money or drugs in the preceding five years.

Do records or other information indicate the potential donor had been incarcerated for more than 72 consecutive hours within the past 12 months?

Do records or other information indicate the potential donor was treated for syphilis, gonorrhea, or other sexually transmitted diseases within the past 12 months?

Do records or other information indicate the potential donor had Creutzfeldt-Jakob disease, neurologic disorders, received injections of human pituitary-derived growth hormone (pit-hGH) or has been transplanted with allograft dura?