DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES

Electronic Laboratory Reporting Onboarding Guide

August 2023

INTRODUCTION

The Electronic Laboratory Reporting (ELR) guide for the State of Montana serves as a guide for facilities when implementing an ELR connection. It is a step-by-step guide that will provide facilities with necessary information about reportable diseases in Montana and how they should be communicated electronically to the Montana Department of Public Health and Human Services (DPHHS). The onboarding process starts with the facility registering their intent through the DPHHS website: https://dphhs.mt.gov/publichealth/meaningfuluse/index

ELR allows facilities to automatically send reportable test results by way of a secure interface to the state disease surveillance system, Montana Infectious Disease Information System (MIDIS). Data are sent by way of standard HL7 2.5.1 messages.

On-Boarding Process Overview

1. Registration
    - Facility completes the Promoting Interoperability registration on DPHHS website https://dphhs.mt.gov/publichealth/meaningfuluse/index
    - After Promoting Interoperability registration is received a Kickoff call between facility, DPHHS, and any other key stakeholders is set up.
2. Connecting and Pre-Testing
    - Understanding HL7 messaging and formatting
    - Identifying required fields
    - Use of LOINC and SNOMED codes
    - Facility provides a key and IP address
    - DPHHS sets up the connection
3. Testing and Validation
    - Test messages are sent to DPHHS
    - DPHHS sends feedback until messages comply with required format
4. Production
    - Live message is sent to PROD
    - DPHHS validates live message
    - Facility can discontinue manual submissions

Montana ELR HL7 2.5.1 Onboarding Process Flow Chart

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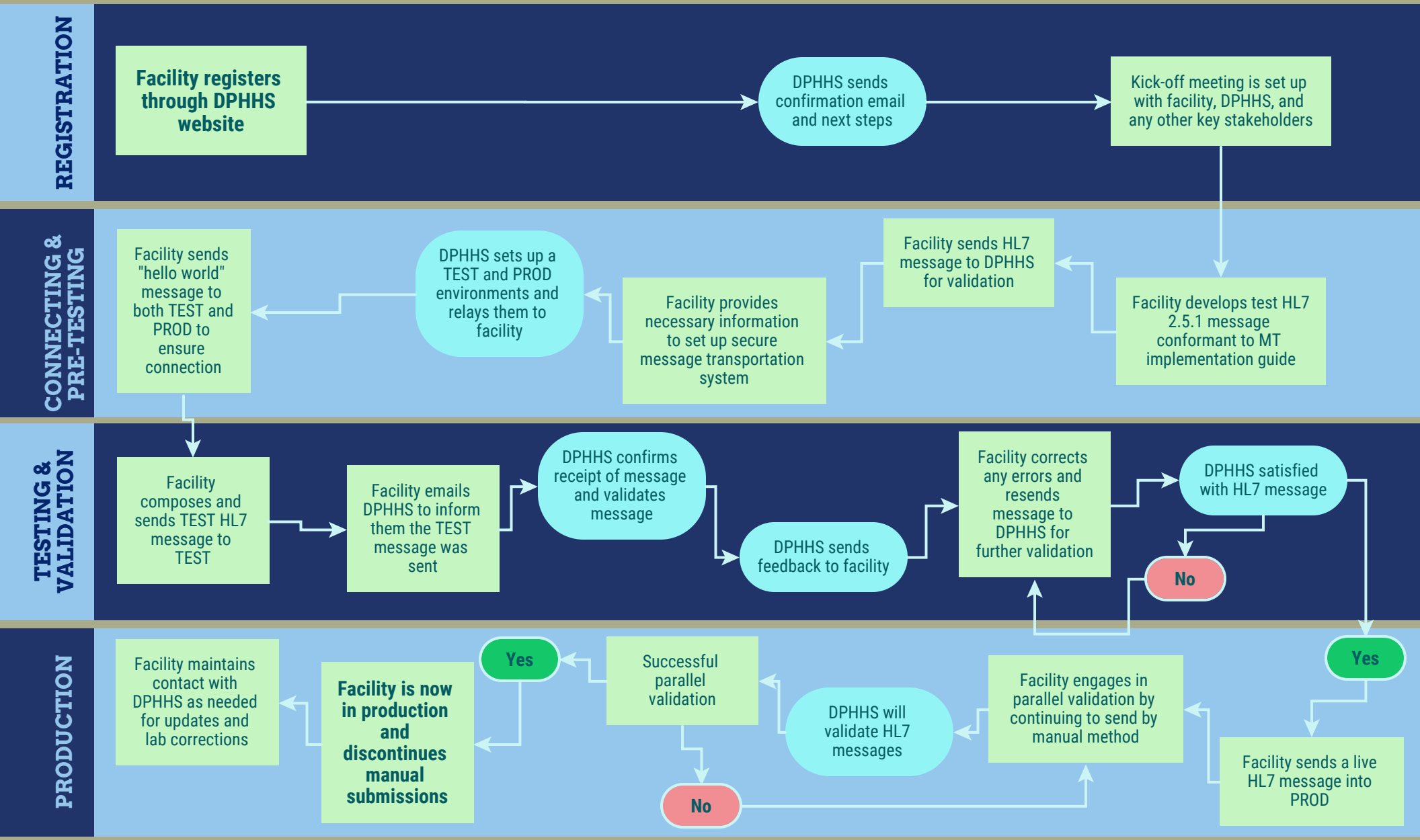

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REGISTRATION

Registering through the DPHHS webpage is the first step in the onboarding process and lets DPHHS know you intend to set up a connection and report labs by way of HL7 messages. DPHHS will then send an email with instructions on next steps and set up a kickoff meeting.

The kickoff meeting should include anyone who will be involved in the process. During the kickoff meeting the group will review the onboarding process, discuss a timeline, identify lead roles, and set up a standing reoccurring meeting.

CONNECTING AND PRE-TESTING

Step 1: Create and Transmit HL7 Messages

Facilities must have the ability to write HL7 messages for ELR onboarding (HL7 formatting explained below). During this phase the facility will provide DPHHS with the necessary information, see figure 1, to set up a connection. DPHHS will then create the connection. Once a connection is made between DPHHS and the onboarding site a "Hello World" message is sent to TEST and PROD to confirm the connection is operational.

Step 2: Select Desired Message Transmission Method

Facilities can send by Secure File Transport Protocol (SFTP) or Public Health Information Network Messaging System (PHINMS). Facilities that select SFTP will be sending to a secured directory setup specifically for them. Access to the directory will be granted by way of the IP address and public key authentication. This requires the service provider to generate an RSA public/private key pair with a passphrase. The IP address will need to be static from the computer intended to send the data files to the State of Montana.

When choosing between SFTP and PHINMS, consider the following:

- Is local support available?
- Is permission required to install SFTP or PHINMS?
- Will firewall rules be affected?

Figure 1. SFTP and PHINMS Authentication

SFTP	
STATE of MT Will Provide	**FACILITY/VENDOR Will Provide**
Login ID Port Number URL Path	Public Key Static IP Address

PHINMS	
STATE of MT Will Provide	**FACILITY/VENDOR Will Provide**
URL Recipient Name Party ID Service Name Service Action Certificate Public Key	Static IP Address PHINMS CPA.xml file Party ID Certificate Public Key

Step 3: Create SSH keypair

-Create a SSH keypair using instructions in Appendix A: Creating Keys

- Send only the **public** key to ELR Coordinator. The private portion should be securely retained at the facility.

Step 4: Create HL7 Message

ELR Message Formatting

Each line of an HL7 message has the same formatting:

<Segment Name>|Text1^Text2^Text3|^Text4^^^Text5|

Required HL7 Segments:

- MSH: Information on reporting laboratory
- PID: Information about the patient
- ORC: Information about the ordering facility
- OBR: Information about the lab report
- OBX: Information about the observation done
- SPM: Information about the specimen

MSH: Information on reporting laboratory

Segment	Name of Field	Possible Example	R= Required
1	Field Separator	|	R
2	Encoding Characters	^&~/	R
3	Sending Application	LIMS	R
4.1	Sending Facility Namespace	Facility Name	R
4.2	Sending Facility Univ. ID	CLIA #	R
4.3	Sending Facility Univ. ID Type	"CLIA"	R
5	Receiving Application	MTDOH	R
6	Receiving Facility	MT	R
7	Date/Time of Message		R
9.1	Message Type/Message Code	ORU	R
9.2	Trigger Event	R01	R
9.3	Message Structure	ORU_R01	R
10	Message Control ID		R
11	Processing ID	(D, T, P)	R
12	Version ID	2.5.1 or 2.3.1	R

Example:

MSH|^~\&|Sending Application|Test Montana Health^852369^CLIA|MTDOH|MT|20230409213215||ORU^R01^ORU_R01|789456123|P|2.5.1|

PID: Information about the patient

Segment	Name of Field	Possible Example	R= Required
1	Set ID	Usually "1"	R
3	Patient Identifier List		R
5.1	Family Name (Last Name)		R
5.2	Given Name (First Name)		R
7	Date/Time of Birth		R
8	Administrative Sex		R
10.1	Race Identifier		R
10.2	Race Text		R
10.3	Race-Name of Coding System	HL70005	R
11.1	StreetAddress		R
11.3	City		R
11.4	State		R
11.5	Zip or Postal Code		R
13.6	Phone Area/City Code		R
13.7	Local Phone Number		R

Example:

PID|1||246810||Dutton^Beth||19010101|F||2131-1^Other Race^HL70005|987 YELLOWSTONE RIVER ROAD^^Missoula^MT^59801||^^^^^406^1234567|

ORC: Information about the ordering facility

Segment	Name of Field	Possible Example	R= Required
1	Order Control	RE	R
3.1	Filler Order Number Entity Identifier		R
3.2	Namespace		R
3.3	Universal ID		R
3.4	Universal ID Type	ISO	R
12.1	Ordering Provider ID Number		P
12.2	Family Name		R
12.3	Given Name		R
14.6	Area Code		R
14.7	Local Number		R
21	Ordering Facility Name		R
22.1	Ordering FacilityAddress/street Address		R
22.3	City		R
22.4	State		R
22.5	Zip		R
23.6	Area Code		R
23.7	Local Number		R
24.1	Ordering Provider Address		R
24.3	City		R
24.4	State		R
24.5	Zip		R

Example:

ORC|RE||1234567^Test Montana Health^2.11.222.1.112233.4^ISO|||||||||4567^Smith^Jane||^^^^^406^4441234|||||||Test Montana Health|123 MAIN ST^^Missoula^MT^59801|^^^^^406^4441234|2018 MAIN ST^^BILLINGS^MT^59105|

OBR: Information about the lab report

Segment	Name of Field	Possible Example	R= Required
1	Set ID		R
3	Filler Order Number	LOINC Code	R
4.1	Identifier		R
4.2	Text	"LN"	R
4.3	Name of Coding System		R
7	Observation Date/Time		R
16.1	Ordering Provider ID number		P
16.2	Family Name		R
16.3	Given Name		R
17.6	Ordering CallBack Phone Number Area Code		R
17.7	Local Number		R
22	Results Rpt/Status Chng-Date/Time		R
25	Result Status	(F,P,C)	R

Example:

OBR|1||9884120|94558-4^SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay^LN|||20230409213215|||||||||4567^Smith^Jane|^^^^^406^4441234|||||20230409213215|||F|

OBX: Information about the observation

Segment	Name of Field	Possible Example	R= Required
1	Set ID		R
2	Value Type		R
3.1	Observaiton Identifier Identifier	LOINC	R
3.2	Text		R
3.3	Name of Coding System		R
5.1	Observation Value SNOMED code	SNOMED	R
5.2	"Detected" "Not Detected"		R
5.3	SCT		R
11	Observation Result Status	(F,C,P)	R
14	Date/Time of the Observation		R
23.1	Performing Oganization name		R
24.1	Performing Oganization Address Street Address		R
24.3	City		R
24.4	State		R
24.5	Zip Code		R

Example:

OBX|1|CWE|94558-4^SARS-CoV-2 (COVID-19) Ag [Presence] in Respiratory specimen by Rapid immunoassay^LN||260415000^Not Detected^SCT||||||F|||20230409213215|||||||||Test

SPM: Information about the Specimen

Segment	Name of Field	Possible Example	R= Required
1	Set ID	1	R
4.1	Specimen Type Identifier	SNOMED Code	R
4.2	Text		R
4.3	Name of Coding System	"SCT"	R
8.1	Specimen Souce Site Identifier		R
8.2	Text		R
8.3	Name of Coding System	"SCT"	R
17	Specimen Collection Date/Time		R
18	Specimen Received Date/Time		R

Example:

SPM|1|||445297001^Swab of internal nose^SCT||||258500001^Nasopharyngeal swab^SCT|||||||||20230409213215|20230409213215|

Transition from Local Codes to Standardized Codes

Many facilities use local codes for collecting patient identifiers, test types, and test results. Many facilities use local codes to identify variables, but those codes are not understandable to outside systems unless the outside system adopts the facilities codes. This can become cumbersome when every facility has their own coding system. A standardized coding system eliminates the need to learn every facility's local coding system. It also allows for cross jurisdictional lab transfer when reportable tests are run on out of state patients.

DPHHS is moving toward only using standardized codes and no longer accepts local codes. DPHHS asks all sending facilities to use LOINC® and SNOMED® codes.

LOINC® http://search.loinc.org/

LOINC® (LN) stands for Logical Observation Identifiers Names and Codes and is the standard coding system for laboratory tests. Many test manufacturers list the proper LOINC to be used with their test kits. Please insure you are using the correct LOINC associated with the test kit.

Test	Local Code	LOINC® (LN)
Chlamydia trachomatis DNA	Facility 1: CT	6357-8
Chlamydia trachomatis DNA	Facility 2: CTDNA	6357-8
Chlamydia trachomatis DNA	Facility 3: CH102	6357-8

LOINC® OBX Example:

OBX|1|CWE|6357-8^Chlamydia trachomatis DNA [Presence] in Urine by NAA with probe detection^LN||10828004^Positive(qualifiervalue)^SCT ||||||F|||202305051830|||||||||KRMC Laboratory^D^^^^CLIA&2.16.840.1.113883.4.7&ISO|310 Sunnyview Lane^^Kalispell^MT^59901^USA^B^^30029

SNOMED® http://www.snomedbrowser.com/

SNOMED® stands for Systemized Nomenclature of Medicine and is a standard coding system for laboratory results.

Result	Local Code	SNOMED® Code (SCT)
Positive	Facility 1: Positive	10828004
Positive	Facility 2: CT Positive	10828004
Positive	Facility 3: CT Detected	10828004

SNOMED® OBX Example:

OBX|1|CWE|6357-8^Chlamydia trachomatis DNA [Presence] in Urine by NAA with probe detection^LN||10828004^Positive(qualifiervalue)^SCT ||||||F|||202305051830|||||||||KRMC

Laboratory^D^^^^CLIA&2.16.840.1.113883.4.7&ISO|310 Sunnyview Lane^^Kalispell^MT^59901^USA^B^^30029

TESTING AND VALIDATION

During testing the facility sends test messages for all reportable disease (link to full list of reportable diseases in FAQ) resulted in their lab. Test labs can contain real patient data or fake data, the TEST site like the PROD site is secure and HIPAA compliant. DPHHS checks all labs and provides feedback. During testing, messages will be reviewed to ensure they contain all required HL7 message segments and Montana DPHHS required fields (for a list of required segments and fields, see the "ELR Formatting" section). If corrections are needed the facility will make the necessary corrections and resend the lab(s) until they are clear for PROD.

Estimated time: testing and validation could take between few days to a few months depending on the number of labs to test and the time it takes to fix errors.

PRODUCTION

When validation is complete the facility moves into PROD. A live message is sent through PROD and DPHHS validates the message was received. The facility continues manually submitting their test results while submitting results through the ELR. This step is to ensure all reportable results are coming through the connection. After a few days of PROD validation, DPHHS will notify the facility that they may discontinue any manual uploading that is no longer necessary.

*It is the facilities responsibility to ensure all reportable conditions are being reported. If the ELR goes down for any reason the facility is responsible for manually reporting all reportable conditions.

FAQ

What diseases are reportable in Montana?

ARM 37.114.203 : REPORTABLE DISEASES AND OTHER CONDITIONS OF PUBLIC HEALTH IMPORTANCE - Administrative Rules of the State of Montana (mt.gov) states what is reportable to local and state public health

ARM 37.114.204 : REPORTS AND REPORT DEADLINES - Administrative Rules of the State of Montana (mt.gov) includes timelines for when reportable conditions must be reported from local health jurisdictions to state public health

- Within 4 hours, 24 hours, or 7 days, depending on the condition.
- Providers must report reportable conditions to local public health 'immediately.'

Who is required to report disease and conditions?

ARM 37.114.201 : REPORTERS - Administrative Rules of the State of Montana (mt.gov) states who the specific reporters of reportable diseases and conditions are.

- Includes physicians, dentists, nurses, medical examiners, school administrators, day care facilities, laboratory professionals, etc.

What should be included in the report?

ARM 37.114.205 : REPORT CONTENTS - Administrative Rules of the State of Montana (mt.gov) details what should be included in the report.

What happens if an ELR connection is disrupted?

It is the facilities responsibility to ensure all reportable conditions are being reported. If the ELR goes down for any reason the facility is responsible for manually reporting all reportable conditions to the local health jurisdiction.

What are ELR Best Practices?

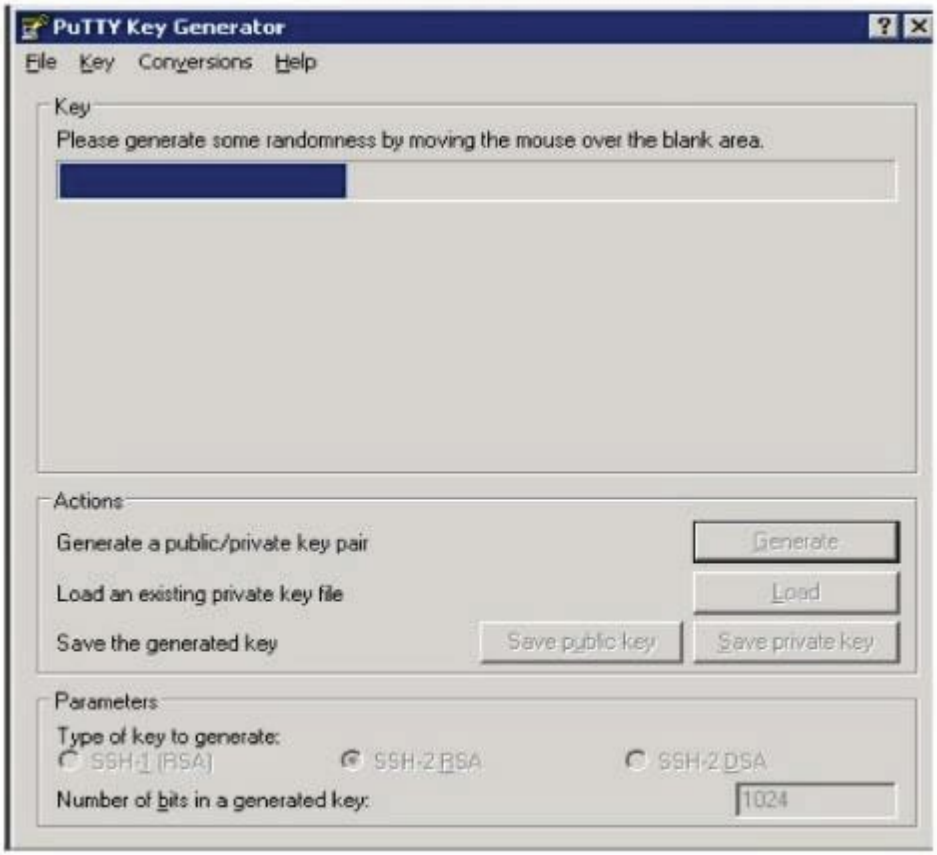
• Narrative or text results are not accepted in the OBX_5 fields.
• Observation values in OBX_5 (as indicated in OBX_2) are constrained to SN and CE data types only.
• LOINC (in OBR_4 and OBX_3) and SNOMED (in OBX_5 when OBX2=CE) are required components
• Clinical Laboratory Improvement Amendment (CLIA) certificate numbers are preferred over the use of OIDS to identify hospitals and laboratory facilities.

Appendix A. Instructions for Creating SSH Key Pair

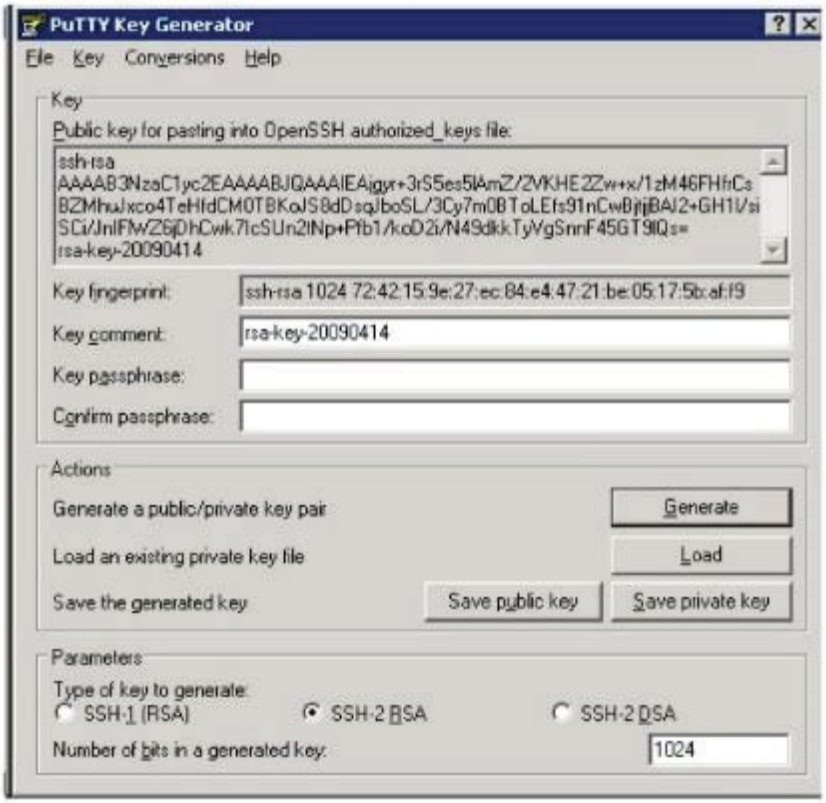
1. Download PuTTYgen
   https://www.chiark.greenend.org.uk/~sgtatham/putty/download.html

2. Run PuTTYgen.exe
   a. Type of key to generate: SSH-2 RSA
   b. Number of bits in a generated key: 2048

3. Click on Generate and move your mouse randomly over the box as instructed.



4. Create a password of your choice.
    a. Enter Key passphrase
    b. Enter Confirm passphrase



5. Click on Save public key
6. Click on Save public key

**Keep your private key secret – do not share with anyone, at any time. **

MONTANA DPHHS

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