

EXHIBIT A – SCOPE OF WORK

I. Purpose:

Summary of Scope

The purpose of this agreement, including its goals and objectives are for the contractor to provide New Mexico Department of Health PHD Pharmacy with a cloud based pharmaceutical Enterprise Resource Planning (ERP) solution tailored to wholesale distributors. The solution will allow for distribution of pharmaceuticals, medical supplies, and medical devices in a manner that is compliant with all applicable state and federal regulations. The solution will have a user-friendly interface, robust reporting capabilities, and will allow for integration with existing contractors. The solution will also support existing internal distribution to DOH entities with minimal disruption of current operations. The full specifications can be found in “Mandatory Specification”, “Desirable Specification” and “Technology Specification”

Background:

DOH PHD Pharmacy distributes pharmaceutical and medical supplies for a wide range of public health initiatives and a statewide network of healthcare providers. The department provides pharmaceutical services to hospitals, private practice clinics, DOH public health offices, opioid prevention and education sites, and family planning provider agreement sites to support routine operations and public health emergency response.

DOH PHD Pharmacy is required to maintain compliance with FDA, DEA, HRSA and NMBOP regulations pertaining to controlled substance, pharmaceutical, medical device, and medical supply distribution.

Licensure:

- New Mexico Board of Pharmacy licensed pharmaceutical wholesale distributor. FDA registered pharmaceutical wholesale distributor.
- New Mexico Board of Pharmacy licensed controlled substance facility. DEA registered controlled substance facility.
 - The department does not currently distribute controlled substances
- The department does not hold licensure or registration as an FDA re-packaging or manufacturing facility

Wholesale Distribution:

- Receipt of pharmaceuticals, medical devices, and medical supplies from multiple suppliers. Distribution of original manufacturer packaged pharmaceuticals, medical devices, and medical supplies to external partners.

Internal Warehousing/Distribution for Entity-Owned Facilities:

- Receipt of pharmaceuticals, medical devices, and medical supplies from multiple suppliers.
- Kitting of medical supplies for internal distribution within DOH.
- Labeling/kitting of unit of use and unit dose pharmaceuticals for internal distribution within DOH owned facilities in compliance with NMBOP requirements

Current Volume/User Accounts:

- 1 Warehouse location
 - 1301 Siler Rd Bldg A, Santa Fe, NM, 87507
- 10 Warehouse users
- 276 Active Ship to locations (this is due to fluctuate at any given time)
 - Ship to locations each have 2-3 individuals placing orders for their location.
- 53 plus multi-item orders processed on average per week
- 10 suppliers of pharmaceuticals and medical supplies

IT Data Migration Needs:

Data migration from a 102MB database on SQL Server 2019 database server running in SQL 2012 compatibility level

MANDATORY SPECIFICATION

Amendment 1

#	Requirement
PH-1	The contractor must submit a business continuity and disaster recovery plan.
PH-2	The solution must be cloud-based.
PH-3	The solution must be fully compliant with all federal and state regulations governing the distribution of medications. Additionally, it must receive regular updates to ensure ongoing regulatory compliance.
PH-4	The solution must be available twenty-four (24) hours a day, seven (7) days a week, 365 days a year, except during scheduled maintenance. The Contractor shall guarantee 99.9% uptime 7 days a week, 24 hours a day, 365 days a year, exclusive of the regularly scheduled maintenance window.
PH-5	The solution must support configurable role-based access. The contractor shall work with the DOH to define mutually agreed-upon user roles and associated access rights.
PH-6	The solution must have a support desk. The support desk must be available a minimum of 6 hours per day on Monday-Friday during the hours of 8AM-5PM MST.
PH-7	The solution must have comprehensive user training.
PH-8	The solution must support real-time inventory management.
PH-9	The solution must support multiple users simultaneously receiving, entering orders, picking orders, and shipping items.
PH-10	<p>The solution must be fully DSCSA compliant for wholesale distribution including but not limited to:</p> <ul style="list-style-type: none"> • Track and Trace (T3) transaction history <ul style="list-style-type: none"> ○ EDI with trading partners. Electronic track and trace reports accessible to trading partners. ○ On 11/27/24, software must comply with section 582(g)(1)(B) of the FD&C Act requiring that the transaction information exchanged include the product identifier at the package level (i.e the

	<p>standardized numerical identifier consisting of the NDC, serial number, lot number, and expiration) for each package included in the transaction.</p> <ul style="list-style-type: none"> • saleable return-verification router service • suspect and illegitimate product handling (quarantine) and return • record retention of a minimum of 6 years
PH-11	<p>The solution must be fully compliant with DEA regulations overseeing the distribution of controlled substances. Including but not limited to:</p> <ul style="list-style-type: none"> • DEA compliant controlled substance ordering system (CSOS) • ARCOS reporting • suspicious order monitoring <p>Note: no control substances are currently processed. However, DOH must have the ability to turn on this feature at a later date.</p>
PH-12	<p>The solution must have the ability to process transactions for medications, medical supplies and medical devices.</p>
PH-13	<p>The solution must allow for the creation of multiple unique SKUS for the same medication/product OR must have another alternative solution that will allow the department to separate inventory based on the program and 340B status (i.e. FP non-340B, STD non-340B, FP 340B, STD 340B, and TB340B). Alternative mechanisms that achieve this goal will be considered.</p>
PH-14	<p>The solution must have the ability to tie specific SKUS to a contract/formulary/program/reporting bundle so that we can pull separate reports for our programs (i.e. BHEM, FP, HR, STD, TB, WIC).</p>
PH-15	<p>The solution must have the ability to tie a specific SKU to a larger bin for reporting purposes.</p> <ul style="list-style-type: none"> ○ example: ability to pull a report for all doxycycline 100mg in inventory. All SKUs linked to this “item class” will generate on the report as opposed to running 6-7 reports based on the individual SKU. ○ Department users must have access to add/remove skus to these reporting bins.
PH-16	<p>The solution must have the ability to assign a warehouse location (i.e. shelf/bin) to inbound inventory</p>
PH-17	<p>The solution must have expiring inventory management features. The features must include the ability to pull reports based on items that will be expiring soon, the ability to remove expiring inventory from the system, and documentation of the removal of the expiring product.</p>

PH-18	The solution must have recall management. The solution must be able to issue a recall notice to all recipients of a product based on the NDC, product number, SKU, and/or lot number
PH-19	The solution must have the ability to receive saleable returns in a manner that is compliant with DSCSA requirements.
PH-20	The solution must have a process in place for handling products that scan as an unsaleable return including documentation regarding disposition.
PH-21	The solution must have the ability to kit medical supplies
PH-22	The solution must have the ability to record shipping carrier and tracking information associated with an outbound order
PH-23	The solution must have the following license management features: <ul style="list-style-type: none"> • ability to track multiple license types including: NMBOP facility license, individual prescriber licenses, controlled substance licenses, CLIA certification, 340B registration) • ability for a ship to site to have multiple license types • ability to restrict controlled substance, prescription only, 340B, CLIA laboratory supplies, and certain medical devices only to sites with the corresponding license or registration • ability to track license expiration date and prohibit shipments to sites with inactive licensure for restricted products
PH-24	The solution must allow some users the ability to ability to add/deactivate trading partners without a ticket to the software vendor.
PH-25	The solution must allow some users the ability to ability to edit trading partner site information without a ticket to the software vendor.
PH-26	The solution must have a location for documenting a single or multiple email addresses for a trading partner contact.
PH-27	The solution must allow for export of all trading partner contact information by DOH.

PH-28	The solution must have the ability to limit specific site ordering to specific formularies/contracts/SKU bundles.
PH-29	The solution must have a verification process built into the order fulfillment workflow to ensure accuracy.
PH-30	The solution must have the ability to scan 2D barcodes utilized in DSCSA compliant labeling.
PH-31	<p>The solution must have the ability to pull the following reports at minimum. Additional reports may be requested upon implementation:</p> <ul style="list-style-type: none"> • view all issuances based on the following criteria: <ul style="list-style-type: none"> ○ lot number ○ NDC ○ ship to location ○ program/formulary/contract/set of SKUs/SKU ○ ability to set time frame for report (i.e 1/1/24-6/30/24) • view all receipts based on the following criteria: <ul style="list-style-type: none"> ○ vendor order number ○ vendor ○ lot number received ○ NDC received ○ program/formulary/contract/set of SKUS/SKU ○ ability to set time frame for report (i.e 1/1/24-6/30/24) • view inventory on hand based on the following criteria: <ul style="list-style-type: none"> ○ all inventory on hand ○ all and/or specific medication(s) on hand ○ all and/or specific supplies on hand ○ all and/or specific medical devices on hand ○ all and/or specific inventory on hand for a specific program/formulary/contract/set of SKUS/SKU ○ expiration date • view products expiring within ## days • report document products removed for expiration <ul style="list-style-type: none"> ○ ability to set timeframe for report (i.e. 1/1/24-6/30/24)

	<ul style="list-style-type: none">• view transaction detail report for a particular SKU.
PH-32	The solution must have the ability to add additional warehouse location(s) at a later date upon the request of DOH.
PH-33	The contractor must submit documentation for any required hardware specifications. This should include all hardware including optional accessories such as scanners, label printers, etc.
PH-34	The contractor must provide data migration services for existing inventory.

DESIRABLE SPECIFICATION

Amendment 1

#	Requirement
PH-35	It is highly desirable for the solution to have a built in DSCSA compliant solution. Integration with a DSCSA compliance solution is acceptable
PH-36	It is highly desirable for the solution to have the ability to link a pdf of the vendor invoice to received product.
PH-37	It is highly desirable for the solution to have the ability to link a pdf of the purchase order to order receipt.
PH-38	It is highly desirable for the solution to have the ability to send a copy of the invoice to customer via email.
PH-39	It is highly desirable for the solution to have an online portal for customers to access their records
PH-40	It is highly desirable for the solution to integrate with pharmaceutical reverse distributor for processing of expiring products.
PH-41	It is highly desirable for the solution to have the ability to track recipient response to a recall notification
PH-42	It is highly desirable for the solution to integrate with FedEx and UPS.
PH-43	It is highly desirable for the solution to have the ability to allow for additional licensure requirements specific to a SKU. For example: SKU for Nexplanon, would require a Nexplanon certificate on file for the receiving location/provider.
PH-44	It is highly desirable for the solution to allow for a pdf licensure verification to each license field. Alternatively, the solution may have functionality to document the date of license verification.
PH-45	It is highly desirable for the solution allow multiple contacts for each ordering location.
PH-46	It is highly desirable for the solution to have a customer ordering portal
PH-47	It is highly desirable for the solution to have a order workflow to track order progress from order receipt, order approval, order picking, order verification, and shipping.
PH-48	It is highly desirable for the solution to allow minimal customization to the invoice. For example, DOH does not bill <u>most</u> customers for the products it ships. It would be helpful to have the ability to selectively add a statement indicating that pricing is for informational purposes only and no charge will be billed.
PH-49	<p>It is highly desirable if the contractor has a solution that will enable DOH to document intra-company transfers between entity owned receiving sites.</p> <ul style="list-style-type: none"> • Example: warehouse ships to clinic A. Clinic A transfers stock to clinic B. All three are owned by the entity. We need a process for documenting stock transfer from Clinic A to Clinic B. • Currently 50 sites would require intracompany transfers. Please note these are not additional warehouse locations.
PH-50	<p>It is highly desirable for the solution to allow for medication “kitting” or a modification of a repackaging module to meet DOH needs for intracompany distribution. The intended purpose is to document labeling/kitting of unit of use and unit dose products for <u>intracompany distribution only</u> in compliance with NMBOP requirements.</p> <p>Example: Boxes of Doxycycline 100mg UD #50 opened and kitted as Doxycycline 100mg UD #20 for internal use.</p>

	Note: NMHealth does not have a repackaging license. Repackaging/kitting module would be utilized only for intracompany distribution, which is exempt from DSCSA regulation. No external distribution would occur for “kitted” medications.
PH-51	It is highly desirable for the solution to allow export of SQL server data or other data source to Nice Label Pro in order to allow for population of labels with lot level medication information for internal distribution. Alternative mechanisms for accomplishing this goal without manual data entry will be considered.
PH-52	It is highly desirable for the solution to allow for documentation of the United Nations Standard Products and Services Code (UNSPSC) of medical supplies and devices
PH-53	It is highly desirable if the solution has a feature that validates authorized trading partner status.
PH-54	It is highly desirable for users to have the ability to create customized reports.
PH-55	<p>It is highly desirable for the solution to pull the following reports:</p> <ul style="list-style-type: none"> • view all issuances based on the following criteria: <ul style="list-style-type: none"> ○ GTIN (Global Trade Item Number) ○ SNI (Standardized Numerical Identifier) • view all receipts based on the following criteria: <ul style="list-style-type: none"> ○ GTIN (Global Trade Item Number) ○ SNI (Standardized Numerical Identifier) • view inventory on hand based on the following criteria: <ul style="list-style-type: none"> ○ GTIN (Global Trade Item Number) ○ SNI (Standardized Numerical Identifier) • report document products removed for expiration <ul style="list-style-type: none"> ○ ability to set timeframe for report (i.e. 1/1/24-6/30/24) ○ ability to pull information for a specific GTIN or SNI. <p>view transaction detail report for a particular GTIN or SNI.</p>

TECHNOLOGY SPECIFICATION

Amendment 1

#	Requirement	Total Points Possible: Pass/Fail
IT-1	All user interfaces must be accessible via an Internet browser, and not require any software to be installed on a client workstation or device except for browser software and drivers required to and similar input/ output (I/O) devices.	Pass/Fail
IT-2	The solution must allow direct access to the database(s) by State employees who possess the proper access rights. These employees must be able to choose from a variety of analytical / query tools (e.g. SAS, SQL Server Management Studio, etc.)	Pass/Fail
IT-3	The solution must run on the two most recently released versions of Internet Explorer (IE), Edge (both pre and post version 78), Firefox, Chrome and Safari, including the versions that are available for Apple's IOS and Android devices.	Pass/Fail
IT-4	The Contractor must provide and maintain separate production, training, test/UAT and development environments.	Pass/Fail
IT-5	The solution must support Active Directory Federated Services (ADFS) Single Sign-On user access control.	Desirable
IT-6	The solution must enforce unique usernames and ID's.	Pass/Fail
IT-7	The solution must provide State employees access to be controlled from NMDOH's and/or PHDs Active Directory via Active Directory Federation Services. All username and password rules will be administered in Active Directory.	Desirable
IT-8	The solution must comply with user account and password requirements (including length, types of required characters, expiration, etc.) for all users who do not have a NMDOH or RLD Active Directory account, according to NMDOH and RLD policies, procedures and rules as set forth by the NMDOH and RLD CSOs. The solution must provide the capability to encrypt passwords in transmission and at rest within the system.	Pass/Fail

IT-9	The solution must include a self-service password reset tool that allows a user to reset a personal password (forgotten or inactive) to unlock that user's account. The solution must provide the capability to email password reset links to a user.	Desirable
IT-10	The solution must include the ability to enforce session timeouts during periods of inactivity. The solution must provide the capability for the State to configure the maximum session inactivity time to meet NMDOH and RLD security policies.	Pass/Fail
IT-11	The solution must not store authentication credentials or sensitive data in its code or unencrypted in databases or files.	Pass/Fail
IT-12	The solution must provide the capability to encrypt all application data and to protect it from unauthorized use when in transit and at rest.	Pass/Fail
IT-13	The Contractor must ensure that any application enhancements or upgrades do not remove or degrade security.	Pass/Fail
IT-14	The Contractor shall develop a security plan encompassing addressing workforce, incident reporting, technical security of information assets throughout lifecycle (creation to destruction).	Pass/Fail
IT-15	The Contractor must ensure that all software and hardware are free of malicious code.	Pass/Fail
IT-16	The Contractor must ensure the application is secure against all flaws outlined in the Open Web Application Security Project (OWASP) Top Ten (http://www.owasp.org/index.php/OWASP_Top_Ten_Project). The Contractor must provide an independent, third-party validation that the application has been hardened and secured as defined by NMDOH and RLD CSOs.	Pass/Fail

IT-17	<p>The Contractor must host the solution in a secure hosting environment on one of the following:</p> <ul style="list-style-type: none"> Microsoft’s Azure Government, Google Cloud Platform for Government, Amazon’s AWS GovCloud (US), or <p>A facility that adheres to Uptime Institute’s Tier III Concurrent Maintenance criteria as provided in <i>Tier Standard Topology</i>*. The facility must maintain the following certifications:</p> <ul style="list-style-type: none"> o Uptime Institute’s Tier III (or Tier IV) Gold Certification of Operational Sustainability o Uptime Institute’s Tier III (or Tier IV) Certification of Constructed Facility. o FedRAMP Moderate Provisional Authority to Operate (P-ATO) o DISA Level 2 Provisional Authorization (PA) <p>*available at: http://uptimeinstitute.com/tierpublication</p>	Desirable
IT-18	The Contractor must operate hosting services on a network or cloud environment offering adequate performance to meet the current and any future business requirements for the State application.	Pass/Fail
IT-19	If redundant Internet connections are not available to the Contractor, then the Internet Provider who provides the internet service to the Contractor must have their service supplied by a vendor that has multiple feeds to ensure that a failure in one of the larger carriers will not cause a failure of the State’s service.	Pass/Fail
IT-20	The Contractor’s network architecture must include redundancy of routers and switches in the Data Center.	Pass/Fail

IT-21	The Contractor must maintain the solution hardware and software in accordance with the specifications, terms, and requirements of the contract and sufficient to run the application.	Pass/Fail
IT-22	The Contractor must repair or replace solution hardware or software, or any portion thereof, so that the system operates in accordance with the specifications, terms, and requirements of the contract.	Pass/Fail
IT-23	The Contractor must monitor the application, database, connectivity, interfaces, and all servers with established performance checks agreed to by the State and must automatically notify both Contractor and State application support personnel twenty-four (24) hours a day, seven (7) days a week, 365 days a year, when abnormalities are detected.	Pass/Fail
IT-24	The Contractor must install and update all server patches, updates, and other utilities within sixty (60) days of their release from the manufacturer unless security risks would create a potential breach, in which case the updates must be installed at the earliest opportunity.	Pass/Fail
IT-25	The Contractor must monitor system, security, and application logs based upon mutually agreed protocols delineated in the final contract.	Pass/Fail
IT-26	The Contractor must manage sharing of data resources based upon mutually agreed protocols delineated in the final contract.	Desirable
IT-27	The Contractor must manage daily backups, data storage, and restore operations. The Contractor must ensure that backups are encrypted in a manner meeting minimum Federal Information Processing Standards (FIPS) 140-2 standards and that they are stored in a facility geographically separate from the Contractor's primary data center.	Pass/Fail
IT-28	The Contractor shall transfer a backup copy of the solution database(s) to NMDOH monthly via Secure File Transfer Protocol (SFTP).	Pass/Fail
IT-29	The Contractor may work with the State to set up a daily data replication process.	Pass/Fail

IT-30	The Contractor must notify the NMDOH and RLD CSOs of all breach of security issues via telephone and in writing within 30 minutes of becoming aware of the issue.	Pass/Fail
IT-31	In instances where the State requires access to the application, database or server resources, the Contractor must provide remote desktop connection to the server through secure protocols such as a Virtual Private Network (VPN) and/or appropriate database management, query and/or browser tools.	Pass/Fail
IT-32	The State shall have unlimited access to submit support requests to Contractor technical support staff – via phone or e-mail or help desk system – twenty-four (24) hours a day, seven (7) days a week, 365 days a year. The Contractor’s response for support must conform to problem resolution escalation procedures that prioritize problems based upon mutually agreed protocols that will be delineated in the final contract.	Pass/Fail
IT-33	All database tables will have a unique identity field.	Pass/Fail
IT-34	The solution’s technical architecture must be documented and the documentation kept updated throughout the contract term. Documentation shall include all aspects of the solution stack from hardware/network platform through database, application and User Interface layers including security aspects, as applicable.	Pass/Fail
IT-35	The Contractor and the Procuring Agency must identify a regularly scheduled maintenance window (such as weekly, monthly, or quarterly) during which all relevant server patches and application upgrades shall be applied (other than emergencies).	Pass/Fail
IT-36	The Contractor must adhere to the NMDOH and RLD change management process of application enhancements and upgrades. The Contractor must submit relevant Change Management Requests (CMR) no less than two (2) weeks prior to production implementation, using standard forms provided by Procuring Agency.	Pass/Fail

IT-37	The Contractor must notify the State representative a minimum of two (2) business days prior to implementation of any changes and/or updates to the solution. The Contractor must provide the State with training on any new features or changes to existing features.	Pass/Fail
IT-38	The Contractor must fully support all solution hardware and software components, including the hosting infrastructure, including licensing and maintenance contracts with respective suppliers and manufacturers at all times. The Contractor must supply all licenses necessary for functioning of applications, including all software and hardware licenses for all environments.	Pass/Fail
IT-39	<p>The Contractor must maintain a record of its activities related to repair or maintenance performed for the State, and must report quarterly on:</p> <ul style="list-style-type: none"> Server up-time All change requests implemented, including Operating System patches All critical outages reported including actual issue and resolution Number of deficiencies reported by class with initial response time and time to resolve. 	Pass/Fail
IT-40	For any outage (when a business function cannot be met by a nonperforming application and there is no work around to the problem) greater than 15 minutes, the Contractor must provide an incident report for the interruption of service to the State. An incident report must document, at a minimum: outage cause, solution implemented, amount of downtime, related communications, suggested support improvements, and suggested solution improvements when the solution has been brought back online. The Contractor must provide the incident report within two (2) weeks of incident resolution.	Pass/Fail

IT-41	The Contractor must allow and support the State to schedule and perform a periodic security assessment and to perform solution testing activities by internal State and external 3rd party auditor.	Pass/Fail
IT-42	The Contractor must submit a Business Continuity and Disaster Recovery Plan. This plan must be tested during the UAT phase and approved by the Procuring Agencies. The plan must be kept up to date to reflect changes to the system servers, application, supporting software, and network infrastructure. This plan will be tested at least once a year to ensure viability and meet expectations for Return Time Objectives (RTO) and Return Point Objectives (RPO).	Pass/Fail
IT-43	The Contractor must develop and submit a plan for State approval to address upgrades or replacement of hardware, software or network infrastructure at least two years prior to one or more of these components reaching End of Life (EOL).	Pass/Fail
IT-44	The Contractor must refresh non-production databases at least every 6 months from the production database to include both application code and program data.	Pass/Fail
IT-45	It is highly desirable that the Contractor develop, use and maintain automated test suites for smoke testing and regression testing.	Pass/Fail

SYSTEM HOSTING EVALUATION QUESTIONNAIRE

Amendment 1

QUESTIONS:

1. Will the proposed solution be hosted in a government-certified cloud? If not, include the type of cloud, such as commercial, private, or hybrid.
2. Who will have administrator access to the architecture and/or application, if applicable?
3. Describe the controls and processes for administrator access.
4. Describe the different security measures defined for the solution such as user access, roles-based security, data access, and file access.
5. How is Personal Identifiable Information (PII) data protected in the solution?
6. Is intrusion detection in place for the solution? If yes, describe.
7. Are there firewalls, access control language (ACL), or virtual devices in place for the separation of presentation, business, and/or data layers of the proposed solution? Who is responsible for managing them? If none of the above are in place, describe why they are not required.
8. If the solution is SaaS, is there a Web Application Firewall (WAF)? If so, list what is defined in your Security Operations Center (SOC). If there is no WAF, describe why it is not required.
9. Does your solution have any batch processing? If so explain the security measures defined.
 - a. Who administers the batch process?

- b. Describe the controls and processes for creating and managing Service Accounts that are used for your batch process to access data and files.
10. Will your solution have a need to connect to the New Mexico state infrastructure for any data exchange? If so, explain.
 - a. Describe the exchange mechanism for example, direct Structured Query Language (SQL) connection, Application Program Interface (API), Comma Separated Value (CSV) file, etc.
 - b. What security channel will be used, for example, HTTPS, VPN, IP whitelist, etc.?
11. What measures do you have to monitor and review security logs/alerts?
12. How will identity management be handled? Will usernames and passwords be encrypted? Can MFA/biometrics be enabled and utilized? Can the application utilize the State of New Mexico identity?
13. Describe encryption key management (if any) for your solution.
14. List the environments that your solution will include, for example, development/test/staging. Do these security controls covered in questions 3, 4, 5, 6, 9, 10, 11, 12, 13, and 15 apply to the environment(s)? If not, explain why.
15. Please also provide the following to be included in the submittal:
 1. A System Architecture Document that includes a summary of the software architecture and different tiers/layers, for example database, application, business, and presentation that are not included in the solution.
 2. A diagram with a written description that illustrates the platforms, networks, peripherals, hardware integration, and separation of database, application, business, and presentation tiers/layers.