CITY OF EL PASO, TEXAS
AGENDA ITEM
DEPARTMENT HEAD'S SUMMARY FORM

AGENDA DATE: 02/01/22
PUBLIC HEARING DATE:

CONTACT PERSON(S) NAME AND PHONE NUMBER: Angela Mora, 915-212-6502

DISTRICT(S) AFFECTED: All Districts

STRATEGIC GOAL: 8

SUBGOAL: 8.1

SUBJECT:

APPROVE a resolution / ordinance / lease to do what? OR AUTHORIZE the City Manager to do what? Be descriptive of what we want Council to approve. Include $ amount if applicable.

That the Mayor be authorized to sign an Interlocal Agreement between the City of El Paso (" City ") and The University of Texas at El Paso (" UTEP "), for a five-year term beginning on the date that City Council approves the Interlocal Agreement, whereby UTEP will provide a pharmacist to assist the City ' s Department of Public Health for a limited number of hours per week; for which the City will pay UTEP an amount not to exceed $36,000.00 per year for a

BACKGROUND / DISCUSSION:

Discussion of the what, why, where, when, and how to enable Council to have reasonably complete description of the contemplated action. This should include attachment of bid tabulation, or ordinance or resolution if appropriate. What are the benefits to the City of this action? What are the citizen concerns?

PRIOR COUNCIL ACTION:

Has the Council previously considered this item or a closely related one?

N/A

AMOUNT AND SOURCE OF FUNDING:

How will this item be funded? Has the item been budgeted? If so, identify funding source by account numbers and description of account. Does it require a budget transfer?

HAVE ALL AFFECTED DEPARTMENTS BEEN NOTIFIED? ◉ **YES** ○ **NO**

PRIMARY DEPARTMENT: Public Health
SECONDARY DEPARTMENT:

********************REQUIRED AUTHORIZATION**********************

DEPARTMENT HEAD: *Angela Mora*

(If Department Head Summary Form is initiated by Purchasing, client department should sign also)

Revised 04/09/2021

RESOLUTION

BE IT RESOLVED BY THE CITY COUNCIL OF THE CITY OF EL PASO:

That the Mayor be authorized to sign an Interlocal Agreement between the City of El Paso ("City") and The University of Texas at El Paso ("UTEP"), for a five-year term beginning on the date that City Council approves the Interlocal Agreement, whereby UTEP will provide a pharmacist to assist the City's Department of Public Health for a limited number of hours per week; for which the City will pay UTEP an amount not to exceed $36,000.00 per year for a maximum compensation not to exceed $175,000.00 over the five-year term.

APPROVED this ___ day of _____, 2022.

THE CITY OF EL PASO:

_____
Oscar Leeser
Mayor

ATTEST:

_____
Laura D. Prine
City Clerk

APPROVED AS TO FORM:

Roberta Brito
Assistant City Attorney

APPROVED AS TO CONTENT:

Angela Mora
Angela Mora, Director
Department of Public Health

STATE OF TEXAS	§	**INTERLOCAL AGREEMENT FOR ASSIGNMENT OF PERSONNEL FOR LOCAL PHARMACIST ASSISTANCE**
	§	
COUNTY OF EL PASO	§	

This Agreement is entered into by and between the **City of El Paso, Texas**, a Texas municipal corporation ("City"), and **The University of Texas at El Paso** ("**University**") Texas State Agency, Texas Public Institution of Higher Education and member institution of The University of Texas System, by and through their duly authorized officials, pursuant to the Interlocal Cooperation Act, Article 79.001 *et seq.*, Texas Government Code.

RECITALS

WHEREAS, the University and the City are local governments as defined in Chapter 791 of the Texas Government Code, and have the authority to enter into this agreement, and have each entered into this agreement in the appropriate manner prescribed by law;

WHEREAS, the University and the City specify that each party paying for the performance of said functions of government shall make those payments from current revenues available to the paying party;

WHEREAS, the City Public Health Department ("Department") has requested the assistance of University in assigning employees, faculty and/or staff who are trained and licensed in among other issues, pharmacist services in accordance with Texas State Board of Pharmacy, Texas Administrative Code, Title 22, Part 15, Chapter 291, Subchapter E, Rules 291.91-94 as described in Exhibit A attached hereto and incorporated herein by reference ("Personnel") to assist the City and Department in the provision of services to the City as authorized under the Texas State Board of Pharmacy, Texas Administrative Code, Title 22, Part 15, Chapter 291, Subchapter E, Rules 291.91-94 ("Program");

WHEREAS, University has available Personnel for said assignment by University to the City and Department;

WHEREAS, the Parties wish to establish interagency cooperation arising from the City and Department requiring additional Personnel from University to assist City and Department in the described activities and efforts of the Program;

WHEREAS, the City and the University believe that the cooperative agreement to assist the City, Department, the public and the taxpayers in the Program is adequate consideration to support this Interlocal Agreement;

NOW THEREFORE, in consideration of the mutual contributions described herein and the mutual covenants and undertakings of the parties, the receipt and sufficiency is hereby acknowledged, the City and the University agree as follows:

I. OBLIGATIONS OF BOTH THE CITY AND UNIVERSITY

A. Designated Liaisons. Each party will assign a responsible liaison and point of contact ("POC") to coordinate, oversee and facilitate the implementation of the Program.

The parties hereby designate the following POC under this Agreement:

For University:
José O. Rivera, PharmD
Dean, University School of Pharmacy
500 W. University Ave
El Paso, TX 79968
Phone: (915) 747-8519
Email: jrivera@utep.edu

For Department:
Angela Mora
Director, Public Health Department
5115 El Paso Dr.
El Paso, TX 79905
Phone (915) 212-6564
Cell: (915) 346-8974
Email: angela.mora@elpasotexas.gov

B. The parties will consult with each other and coordinate with their respective POCs to determine available University Personnel capacity.

C. During the term of this Agreement, University will provide to City, in accordance with the Program, the services as set forth in Exhibit "A", performed by the Personnel listed in Exhibit B of this Agreement, attached hereto and incorporated herein by reference, to the Department under the direction and supervision of City's Annett Gonzalez for a period not to exceed **eight (8) hours per week** during the period established herein.

D. Department shall provide all assigned Personnel Department facility orientation and training and shall document said training in accordance with applicable law and regulation. While assigned to Department, Personnel shall follow and comply with the Department's guidelines, Standard Operating Procedures and Safety instructions and Expectations under the Program, including yet not limited to those established in Exhibit A attached hereto and incorporated herein by reference.

E. Personnel shall be assigned to work at the Department or other department and/or City facility as determined by the Department.

F. The City shall be responsible for providing the necessary testing and safety equipment ("Equipment") for the activities under the Program. Any costs associated with providing the Equipment will be paid directly by the City.

G. Subject to receipt of the invoice and substantiating documentation as required under this Agreement and applicable law and regulation, City will reimburse University for the services of Personnel provided by University to City in accordance with Exhibit "B" attached hereto and incorporated herein by reference. The parties expressly agree that any change in Personnel or additional Personnel will require the establishment of an individual rate per person assigned and incorporation in Exhibit B of this Agreement through an amendment of the Agreement.

i) To receive reimbursement, University must submit an invoice to City providing a

description of the services performed and the number of hours worked by Personnel.

ii) University will submit an invoice on a monthly basis. University will submit the invoice to the following address:
City of El Paso Department of Public Health
C/O Deborah Olivas
5115 El Paso Dr.
El Paso, Texas 79905

iii) After review and approval of the invoice submitted by University, City will remit reimbursement to University at the following address:
The University of Texas at El Paso
Attn: Vice President of Business Affairs – Payroll
500 W. University Avenue
El Paso, TX 79968

iv) City agrees to remit reimbursement to University no later than thirty (30) calendar days after City's receipt of the invoice and substantiating documentation.

iv) In no event shall the total amount paid by City under this Agreement exceed $36,000.00 per year or $175,000.00 over the term of this Agreement.

II. OBLIGATIONS OF UNIVERSITY

A. The University shall be responsible for assigning University Personnel and paying its Personnel salary and benefits in accordance with University policy, rules and regulations.

B. During the term of this Agreement and their assignment to City, Personnel will remain at all times employees of University. University shall be responsible for the salary and benefits of Personnel as applicable to employees of University, and shall withhold and transmit payroll taxes, provide unemployment insurance, and workers' compensation benefits as well as process unemployment and workers' compensation claims involving Personnel. For no purposes will Personnel be considered an employee of City.

III. OTHER COVENANTS AND AGREEMENTS

A. Transfer of Ownership Interest. This Interlocal Agreement represents an agreement for the City and University to share resources. Neither party shall acquire an interest in the real or personal property of the other.

B. Retention of Ownership. Upon termination of this Agreement, in accordance with section V, each party will retain ownership of its respective properties, equipment and related supplies, whether or not the property was previously shared, and all Personnel will return to work at University to their regular appointments and assignments.

C. Responsibility for Third Party Contracts. If either party enters into a license, lease, lease/purchase agreement for services, equipment or software, the signing party shall remain responsible for all payments and interaction with the vendor. No contribution will be required from the non-signing entity unless otherwise agreed.

D. Insurance. Each entity may insure its own property, and neither party shall be liable for loss or damage to the real or personal property, personal injury, or any other special, indirect and/or consequential damages of any kind of the other arising from this Agreement.

E. No Conveyance of Real or Personal Property Interests. Both parties agree this Interlocal Agreement is not intended to form an interest in real property and neither the City nor the University will acquire rights of tenancy in the other's facility for the initial term of this Agreement or during any renewal, extensions or modifications of the term of the Agreement.

F. Stand Alone Agreement. The terms of this Agreement will be considered separate from any other University/City transaction or agreement. The mutual consideration of the Parties described herein shall be calculated without reference to any other contract. Setoffs against other contractual obligations is neither contemplated by the parties nor permitted.

IV. INITIAL TERM AND RENEWAL

A. Term and Automatic Renewal. This effective date of this Agreement is the date this Interlocal Agreement is approved by the El Paso City Council ("Effective Date"). The University's responsibility under this Agreement to assign Personnel and services as established herein will commence on the Effective Date ("Commencement Date"). Thereafter, this Agreement shall be in effect for five (5) years beginning on the Effective Date, unless terminated by either party in writing signed by duly authorized representatives of each of the parties in accordance with the same provisions set in this Agreement.

V. TERMINATION

A. Termination for Convenience. Either party may terminate this Agreement for any reason by sending a written notice to the non-terminating party at least fifteen (15) calendar days before termination. All parties providing work under this Agreement will halt all work when the termination notice sent by the terminating party is received by the non-terminating party.

B. Termination by Either Party for Cause. Either party may terminate this Agreement if one party fails to fulfill the obligations set out in this Agreement. Before terminating this Agreement pursuant to this provision, the terminating party will provide written notice of intent to terminating enumerating the failures for which the termination is being sought and provide at least thirty (30) calendar days to the non-terminating party to cure such failure.

C. Non-Appropriation of Funds. Resources for implementation of this Agreement may come from either party, depending upon budgetary availability. Neither party is obligated to expend any resources in connection with this Agreement unless specifically stated otherwise in the Agreement. No implementation of any portion of the Agreement may be initiated prior to the written assurance of such budgetary availability to the other party hereto. To the extent any external funding is required by a party in order to implement this Agreement and funding for such purposes is not appropriated to that party or is not otherwise available to the corresponding party, said party shall have no further financial obligations upon such determination. Should either party not have funding to carry out any obligations of a particular effort conducted under this Agreement, it shall immediately notify the other party of such fact

and of such portions of the Agreement that may be deemed terminated or modified due to lack of funding.

VI. GOVERNMENTAL FUNCTION AND IMMUNITY

A. Governmental Function. The City and University expressly agree that, in all things relating to this Interlocal Agreement, the parties enter into this Interlocal Agreement for the purpose of performing governmental functions and are performing governmental functions, as defined by the Texas Tort Claims Act. The parties further expressly agree that every act or omission of each party, which in any way pertains to or arises out of this Agreement, falls within the definition of governmental function.

B. Immunity. The City and University reserve, and do not waive, their respective rights of governmental and/or sovereign immunity and similar rights and do not waive their rights under the Texas Tort Claims Act. The parties expressly agree that neither party waives, nor shall be deemed hereby to waive, any immunity or defense that would otherwise be available to it against claims arising in the exercise of its powers or functions or pursuant to the Texas Tort Claims Act or other applicable statutes, laws, rules, or regulations.

VII. RISK ALLOCATION – LIMITATION OF LIABILITY

A. Exclusion of Incidental and Consequential Damages. Independent of, severable from, and to be enforced independently of any other enforceable or unenforceable provision of this Agreement, neither party shall be liable to the other party (nor to any person claiming rights derived from such party's rights) for incidental, consequential, special, punitive, or exemplary damages of any kind - including lost profits, loss of business, and further including, mental anguish, emotional distress and attorney's fees- as a result of breach of any term of this Agreement, regardless of whether the party was advised, had other reason to know, or in fact knew of the possibility thereof, except as expressly provided herein. Neither party hereto shall be liable to the other party or any third party by reason of any inaccuracy, incompleteness, or obsolescence of any information provided or maintained by the other party regardless of whether the party receiving said information from the other party was advised, had other reason to know, or in fact knew thereof.

B. Intentional Risk Allocation. The City and University each acknowledge that the provisions of this Agreement were negotiated to reflect an informed, voluntary allocation between them of all risks (both known and unknown) associated with the transactions associated with this Agreement. The disclaimers and limitations in this Agreement are intended to limit the circumstances of liability. The remedy limitations, and the limitations of liability, are separately intended to limit the forms of relief available to the parties.

C. No Indemnification. The City and University expressly agree that, except as provided herein, neither Party shall have the right to seek indemnification or contribution from the other Party for any losses, costs, expenses, or damages directly or indirectly arising, in whole or part, from this Agreement. Each party must handle any claims resulting from their actions in this Agreement. The parties agree that each will be responsible for the acts or omissions of its respective representatives.

D. Fines and Penalties. Each party shall be solely responsible for fiscal penalties, fines or any other sanctions occasioned as a result of a finding that violations of any applicable local, state or federal regulations, codes or laws occurred as a result of that parties actions, except as may be specifically provided by law.

VIII. GENERAL PROVISIONS

A. Compliance with Laws. In the performance of their obligations under this Agreement, the parties shall comply with all applicable federal, state or local laws, ordinances and regulations and declarations.

B. Governing Law. For purposes of determining the law governing the same, this Agreement is entered into in the city and state of main operations of the Parties hereto, and shall be governed by the laws of the State of Texas. Venue shall be in El Paso, Texas.

C. Notices. The parties will send all notices required by this Agreement, in writing, to the other entity by certified mail, return receipt requested at the following addresses:

To the City of El Paso:	City of El Paso Office of the City Manager P.O. Box 1890 El Paso, TX 79950-1890
With copy to:	City of El Paso Director, Public Health Department Angela Mora 5115 El Paso Dr. El Paso, Texas 79905
Agency Name:	The University of Texas at El Paso 500 W. University Ave El Paso, TX 79968 Attn. Vice President for Business Affairs

Changes may be made to the above addresses and addressees through timely written notice provided to the other party.

D. Privileges and Immunities. All privileges and immunities from liability, exemptions from laws, ordinances and rules, pension, relief, disability, worker's compensation, and other benefits which apply to the activities of officers, agents, or employees of the City and the University when performing a function shall apply to such officers, agents, Personnel or employees to the same extent while engaged in the performance of any of their functions and duties under the terms and provisions of this Agreement.

E. Current Revenues. Pursuant to Section 791.011(d) (3), Texas Government Code, each party paying for the performance of governmental functions or services will make those payments from current revenues available to the paying party.

F. No Waiver. The failure of either party at any time to require performance by the other party of any provision of this Agreement shall in no way affect the right of such party to require performance of that provision. Any waiver by either party of any breach of any provision of this Agreement shall not be construed as a waiver of any continuing or succeeding breach of such provision, a waiver or the provision itself, or a waiver of any right under this Agreement.

G. Amendment; Assignability. This Agreement and the obligations hereunder shall not be amended, assigned, transferred or encumbered, in any manner without the written consent of the other party.

H. Severability. All agreements and covenants contained in this Agreement are severable. Should any term or provision of this Agreement be declared illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement will not be affected; and in lieu of each provision which to be illegal, invalid or unenforceable, there will be added as part of this Agreement, a provision which preserves the intention of the unenforceable provision, but which complies with the law.

I. Section Headings. The paragraph or section headings contained in this Agreement are for reference purposes only and shall not in any way control the meaning or interpretation of this Agreement.

J. Representation of Counsel; Mutual Negotiation. Each party has had the opportunity to be represented by counsel of its choice in negotiating this Agreement. This Agreement shall therefore be deemed to have been negotiated and prepared at the joint request, direction, and construction of the parties, at arms' length, with the advice and participation of counsel, and will be interpreted in accordance with its terms without favor to any party.

K. Independent Contractor Relationship. This Agreement does not create an employee-employer relationship between parties. As such, the City is not subject to the liabilities or obligations the University obtains under the performance of this Agreement.

L. Auditing Records for the Specific Project. Subject to applicable law and limitations, the parties will allow the reasonable inspection and copying of all records pertaining to the obligations arising from this Agreement.

M. Force Majeure. There is no breach of contract should either party's obligations within this Agreement be delayed due to an act of God, outbreak of hostilities, riot, civil disturbance, acts of terrorism, the act of any government or authority, fire, explosion, flood, theft, malicious damage, strike, lockout, or any cause or circumstances whatsoever beyond either party's reasonable control. The delayed party must resume performing its obligations in this Agreement after the reason for the delay is resolved.

N. Third-Party Beneficiaries. There are no third-party beneficiaries to this Agreement.

O. Provisions Surviving This Agreement. Representations, releases, warranties covenants, indemnities, and confidentiality survive past the execution, performance, and termination of this Agreement.

P. Representations and Warranties. The persons executing this Agreement on behalf of each of the parties warrant they have sufficient authority to sign on behalf of their respective parties.

Q. Entire Agreement. This Agreement constitutes the entire agreement between the parties.

IN WITNESS WHEREOF, this Agreement has been executed by the parties named hereinabove as of the dates established below.

(Signatures follow on next page)

CITY OF EL PASO

Tomás González
City Manager
Date: _____

ATTEST:

Laura Prine
City Clerk

APPROVED AS TO FORM:

Roberta Brito
Assistant City Attorney

APPROVED AS TO CONTENT:

Angela Mora, Director
Department of Public Health

THE UNIVERSITY OF TEXAS AT EL PASO

Mark McGurk
Vice President for Business Affairs

EXHIBIT A

City of El Paso, Department of Public Health Expectations for Personnel

Personnel is to provide services according to Texas State Board of Pharmacy, Texas Administrative Code, Title 22, Part 15, Chapter 291, Subchapter E, Rules 291.91-94 as follows:

Class D Operating Standards

(a) Registration.

(1) Licensing requirements.

(A) All clinic pharmacies shall register with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) All clinic pharmacies shall provide a copy of their policy and procedure manual, which includes the formulary, to the board with the initial license application.

(C) The following fees will be charged.

(i) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance of a new license and for each renewal.

(ii) A pharmacy operated by the state or a local government that qualifies for a Class D license is not required to pay a fee to obtain a license.

(D) A Class D pharmacy which changes ownership shall notify the board within ten days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(E) A clinic pharmacy shall notify the board in writing of any change in name or location as specified in §291.3 of this title.

(F) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(G) A clinic pharmacy shall notify the board in writing within 10 days of a change of the pharmacist-in-charge or staff pharmacist or consultant pharmacist.

(H) A Class D pharmacy shall notify the board in writing within ten days of closing, following the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).

(2) Registration requirements for facilities that operate at temporary clinic sites. A facility that operates a clinic at one or more temporary locations may be licensed as a Class D pharmacy and provide dangerous drugs from these temporary locations provided:

(A) the Class D pharmacy complies with the registration requirements in paragraph (1) of this subsection;

(B) the Class D pharmacy has a permanent location where all dangerous drugs and records are stored;

(C) no dangerous drugs are stored or left for later pickup by the patient at the temporary location(s), and all drugs are returned to the permanent location each day and stored:

(i) within the Class D pharmacy; or

(ii) within the pharmacy's mobile unit provided the mobile clinic is parked at the location of the clinic pharmacy in a secure area with adequate measures to prevent unauthorized access, and the drugs are maintained at proper temperatures;

(D) the permanent location is the address of record for the pharmacy;

(E) the facility has no more than six temporary locations in operation simultaneously;

(F) the Class D pharmacy notifies the board of the locations of the temporary locations where drugs will be provided and the schedule for operation of such clinics; and

(G) the Class D pharmacy notifies the board within 10 days of a change in address or closing of a temporary location or a change in schedule of operation of a clinic.

(b) Environment.

(1) General requirements.

(A) The Class D pharmacy shall have a designated area(s) for the storage of dangerous drugs and/or devices.

(B) No person may operate a pharmacy which is unclean, unsanitary, or under any condition which endangers the health, safety, or welfare of the public.

(C) The Class D pharmacy shall comply with all federal, state, and local health laws and ordinances.

(D) A sink with hot and cold running water shall be available to all pharmacy personnel and shall be maintained in a sanitary condition at all times.

(2) Security.

(A) Only authorized personnel may have access to storage areas for dangerous drugs and/or devices.

(B) All storage areas for dangerous drugs and/or devices shall be locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals.

(C) The pharmacist-in-charge shall be responsible for the security of all storage areas for dangerous drugs and/or devices including provisions for adequate safeguards against theft or diversion of dangerous drugs and devices, and records for such drugs and devices.

(D) The pharmacist-in-charge shall consult with clinic personnel with respect to security of the pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous drugs and/or devices, and records for such drugs and/or devices.

(E) Housekeeping and maintenance duties shall be carried out in the pharmacy, while the pharmacist-in-charge, consultant pharmacist, staff pharmacist, or supportive personnel is on the premises.

(c) Equipment. Each Class D pharmacy shall maintain the following equipment and supplies:

(1) if the Class D pharmacy prepackages drugs for provision:

(A) a typewriter or comparable equipment; and

(B) an adequate supply of child-resistant, moisture-proof, and light-proof containers and prescription, poison, and other applicable identification labels used in dispensing and providing of drugs;

(2) if the Class D pharmacy maintains dangerous drugs requiring refrigeration and/or freezing, a refrigerator and/or freezer;

(3) if the Class D pharmacy compounds prescription drug orders, a properly maintained Class A prescription balance (with weights) or equivalent analytical balance. It is the responsibility of the pharmacist-in-charge to have such balance inspected at least every three years by the appropriate authority as prescribed by local, state, or federal law or regulations.

(d) Library. A reference library shall be maintained which includes the following in hard copy or electronic format:

(1) current copies of the following:

(A) Texas Pharmacy Act and rules; and

(B) Texas Dangerous Drug Act;

(2) current copies of at least two of the following references:

(A) Facts and Comparisons with current supplements;

(B) AHFS Drug Information;

(C) United States Pharmacopeia Dispensing Information (USPDI);

(D) Physician's Desk Reference (PDR);

(E) American Drug Index;

(F) a reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;

(G) reference texts in any of the following subjects: toxicology, pharmacology, or drug interactions; or

(H) reference texts pertinent to the major function(s) of the clinic.

(e) Drugs and devices.

(1) Formulary.

(A) Each Class D pharmacy shall have a formulary which lists all drugs and devices that are administered, dispensed, or provided by the Class D pharmacy.

(B) The formulary shall be limited to the following types of drugs and devices, exclusive of injectable drugs for administration in the clinic and nonprescription drugs, except as provided in subparagraph (D) of this paragraph:

(i) anti-infective drugs;

(ii) musculoskeletal drugs;

(iii) vitamins;

(iv) obstetrical and gynecological drugs and devices;

(v) topical drugs; and

(vi) serums, toxoids, and vaccines.

(C) The formulary shall not contain the following drugs or types of drugs:

(i) Nalbuphine (Nubain);

(ii) drugs used to treat erectile dysfunction; and

(iii) Schedule I - V controlled substances.

(D) Clinics with a patient population which consists of at least 80% indigent patients may petition the board to operate with a formulary which includes types of drugs and devices, other than those listed in subparagraph (B) of this paragraph based upon documented objectives of the clinic, under the following conditions.

(i) Such petition shall contain an affidavit with the notarized signatures of the medical director, the pharmacist-in-charge, and the owner/chief executive officer of the clinic, and include the following documentation:

(I) the objectives of the clinic;

(II) the total number of patients served by the clinic during the previous fiscal year or calendar year;

(III) the total number of indigent patients served by the clinic during the previous fiscal year or calendar year;

(IV) the percentage of clinic patients who are indigent, based upon the patient population during the previous fiscal year or calendar year;

(V) the proposed formulary and the need for additional types of drugs based upon objectives of the clinic; and

(VI) if the provision of any drugs on the proposed formulary require special monitoring, the clinic pharmacy shall submit relevant sections of the clinic's policy and procedure manual regarding the provision of drugs that require special monitoring.

(ii) Such petition shall be resubmitted every two years in conjunction with the application for renewal of the pharmacy license.

(I) Such renewal petition shall contain the documentation required in clause (i) of this subparagraph.

(II) If at the time of renewal of the pharmacy license, the patient population for the previous fiscal year or calendar year is below 80% indigent patients, the clinic shall be required to submit an application for a Class A pharmacy license or shall limit the clinic formulary to those types of drugs and devices listed in subparagraph (B) of this paragraph.

(iii) If a Class D pharmacy wishes to add additional drugs to the expanded formulary, the pharmacy shall petition the board in writing prior to adding such drugs to the formulary. The petition shall identify drugs to be added and the need for the additional drugs based upon objectives of the clinic as specified in clause (i) of this subparagraph.

(iv) The following additional requirements shall be satisfied for clinic pharmacies with expanded formularies.

(I) Supportive personnel who are providing drugs shall be licensed nurses or practitioners.

(II) The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall make on-site visits to the clinic at least monthly.

(III) If the pharmacy provides drugs which require special monitoring (i.e., drugs which require follow-up laboratory work or drugs which should not be discontinued abruptly), the pharmacy

shall have policies and procedures for the provision of the prescription drugs to patients and the monitoring of patients who receive such drugs.

(IV) The pharmacist-in-charge, consultant pharmacists, or staff pharmacists shall conduct retrospective drug regimen reviews of a random sample of patients of the clinic on at least a quarterly basis. The pharmacist-in-charge shall be responsible for ensuring that a report regarding the drug regimen review, including the number of patients reviewed, is submitted to the clinic's medical director and the pharmacy and therapeutics committee of the clinic.

(V) If a pharmacy provides antipsychotic drugs:

(-a-) a practitioner of the clinic shall initiate the therapy;

(-b-) a practitioner shall monitor and order ongoing therapy; and

(-c-) the patient shall be physically examined by the practitioner at least on a yearly basis.

(v) The board may consider the following items in approving or disapproving a petition for an expanded formulary:

(I) the degree of compliance on past compliance inspections;

(II) the size of the patient population of the clinic;

(III) the number and types of drugs contained in the formulary; and

(IV) the objectives of the clinic.

(2) Storage.

(A) Drugs and/or devices which bear the words "Caution, Federal Law Prohibits Dispensing without prescription" or "Rx only" shall be stored in secured storage areas.

(B) All drugs shall be stored at the proper temperatures, as defined in §291.15 of this title (relating to Storage of Drugs).

(C) Any drug or device bearing an expiration date may not be provided, dispensed, or administered beyond the expiration date of the drug or device.

(D) Outdated drugs or devices shall be removed from stock and shall be quarantined together until such drugs or devices are disposed.

(E) Controlled substances may not be stored at the Class D pharmacy.

(3) Drug samples.

(A) Drug samples of drugs listed on the Class D pharmacy's formulary and supplied by manufacturers shall be properly stored, labeled, provided, or dispensed by the Class D pharmacy in the same manner as prescribed by these sections for dangerous drugs.

(B) Samples of controlled substances may not be stored, provided, or dispensed in the Class D pharmacy.

(4) Prepackaging and labeling for provision.

(A) Drugs may be prepackaged and labeled for provision in the Class D pharmacy. Such prepackaging shall be performed by a pharmacist or supportive personnel under the direct supervision of a pharmacist and shall be for the internal use of the clinic.

(B) Drugs must be prepackaged in suitable containers.

(C) The label of the prepackaged unit shall bear:

(i) the name, address, and telephone number of the clinic;

(ii) directions for use, which may include incomplete directions for use provided:

(I) labeling with incomplete directions for use has been authorized by the pharmacy and therapeutics committee;

(II) precise requirements for completion of the directions for use are developed by the pharmacy and therapeutics committee and maintained in the pharmacy policy and procedure manual; and

(III) the directions for use are completed by practitioners, pharmacists, or licensed nurses in accordance with the precise requirements developed under subclause (II) of this clause;

(iii) name and strength of the drug--if generic name, the name of the manufacturer or distributor of the drug;

(iv) quantity;

(v) lot number and expiration date; and

(vi) appropriate ancillary label(s).

(D) Records of prepackaging shall be maintained according to §291.94(c) of this title (relating to Records).

(5) Labeling for provision of drugs and/or devices in an original manufacturer's container.

(A) Drugs and/or devices in an original manufacturer's container shall be labeled prior to provision with the information set out in paragraph (4)(C) of this subsection.

(B) Drugs and/or devices in an original manufacturer's container may be labeled by:

(i) a pharmacist in a pharmacy licensed by the board; or

(ii) supportive personnel in a Class D pharmacy, provided the drugs and/or devices and control records required by §291.94(d) of this title are quarantined together until checked and released by a pharmacist.

(C) Records of labeling for provision of drugs and/or devices in an original manufacturer's container shall be maintained according to §291.94(d) of this title.

(6) Provision.

(A) Drugs and devices may only be provided to patients of the clinic.

(B) At the time of the initial provision, a licensed nurse or practitioner shall provide verbal and written information to the patient or patient's agent on side effects, interactions, and precautions concerning the drug or device provided. If the provision of subsequent drugs is delivered to the patient at the patient's residence or other designated location, the following is applicable:

(i) Written information as specified in subparagraph (B) of this paragraph shall be delivered with the medication.

(ii) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(iii) The pharmacy shall use a delivery system which is designed to ensure that the drugs are delivered to the appropriate patient.

(C) The provision of drugs or devices shall be under the continuous supervision of a pharmacist according to standing delegation orders or standing medical orders and in accordance with written policies and procedures and completion of the label as specified in subparagraph (G) of this paragraph.

(D) Drugs and/or devices may only be provided in accordance with the system of control and accountability for drugs and/or devices provided by the clinic; such system shall be developed and supervised by the pharmacist-in-charge.

(E) Only drugs and/or devices listed in the clinic formulary may be provided.

(F) Drugs and/or devices may only be provided in prepackaged quantities in suitable containers and/or original manufacturer's containers which are appropriately labeled as set out in paragraphs (4) and (5) of this subsection.

(G) Such drugs and/or devices shall be labeled by a pharmacist licensed by the board; however, when drugs and/or devices are provided under the supervision of a physician according to standing delegation orders or standing medical orders, supportive personnel may at the time of provision print on the label the following information or affix an ancillary label containing the following information:

(i) patient's name; however, the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(ii) any information necessary to complete the directions for use in accordance with paragraph (4)(C)(ii) of this subsection;

(iii) date of provision; and

(iv) practitioner's name.

(H) Records of provision shall be maintained according to §291.94(e) of this title.

(I) Controlled substances may not be provided or dispensed.

(J) Non-sterile preparations may only be provided by the clinic pharmacy in accordance with §291.131 of this title (relating to Pharmacies Compounding Non-sterile Preparations).

(7) Dispensing. Dangerous drugs may only be dispensed by a pharmacist pursuant to a prescription order in accordance with §§291.31 - 291.35 of this title (relating to Community Pharmacy (Class A)) and §291.131 of this title.

(f) Pharmacy and therapeutics committee.

(1) The clinic pharmacy shall have a pharmacy and therapeutics committee, which shall be composed of at least three persons and shall include the pharmacist-in-charge, the medical director of the clinic, and a person who is responsible for provision of drugs and devices.

(2) The pharmacy and therapeutics committee shall develop the policy and procedure manual.

(3) The pharmacy and therapeutics committee shall meet at least annually to:

(A) review and update the policy and procedure manual; and

(B) review the retrospective drug utilization review reports submitted by the pharmacist-in-charge if the clinic pharmacy has an expanded formulary.

(g) Policies and procedures.

(1) Written policies and procedures shall be developed by the pharmacy and therapeutics committee and implemented by the pharmacist-in-charge.

(2) The policy and procedure manual shall include, but not be limited to, the following:

(A) a current list of the names of the pharmacist-in-charge, consultant-pharmacist, staff pharmacist(s), supportive personnel designated to provide drugs or devices, and the supportive personnel designated to supervise the day-to-day pharmacy related operations of the clinic in the absence of the pharmacist;

(B) functions of the pharmacist-in-charge, consultant pharmacist, staff pharmacist(s), and supportive personnel;

(C) objectives of the clinic;

(D) formulary;

(E) a copy of written agreement between the pharmacist-in-charge and the clinic;

(F) date of last review/revision of policy and procedure manual; and

(G) policies and procedures for:

(i) security;

(ii) equipment;

(iii) sanitation;

(iv) licensing;

(v) reference materials;

(vi) storage;

(vii) packaging-repackaging;

(viii) dispensing;

(ix) provision;

(x) retrospective drug regimen review;

(xi) supervision;

(xii) labeling-relabeling;

(xiii) samples;

(xiv) drug destruction and returns;

(xv) drug and device procuring;

(xvi) receiving of drugs and devices;

(xvii) delivery of drugs and devices;

(xviii) recordkeeping; and

(xix) inspection.

(h) Supervision.

The pharmacist-in-charge, consultant pharmacist, or staff pharmacist shall personally visit the clinic on at least a monthly basis to ensure that the clinic is following established policies and procedures. However, clinics operated by state or local governments and clinics funded by government sources money may petition the board for an alternative visitation schedule under the following conditions:

(1) Such petition shall contain an affidavit with the notarized signatures of the medical director, the pharmacist-in-charge, and the owner/chief executive officer of the clinic, which states that the clinic has a current policy and procedure manual on file, has adequate security to prevent diversion of dangerous drugs, and is in compliance with all rules governing Class D pharmacies.

(2) The board may consider the following items in determining an alternative schedule:

(A) the degree of compliance on past compliance inspections;

(B) the size of the patient population of the clinic;

(C) the number and types of drugs contained in the formulary; and

(D) the objectives of the clinic.

(3) Such petition shall be resubmitted every two years in conjunction with the application for renewal of the pharmacy license.

In addition, as part of the Program, Personnel shall precept University School of Pharmacy students as part of the University students' educational program experiential requirements.

EXHIBIT B

Personnel

1. For the period beginning on the effective date of this Agreement and ending on August 31, 2022, **Sara Smith** ("Professor Smith"), Professor of Pharmacy Practice and Clinical Sciences in the University's School of Pharmacy, will provide services in Exhibit A at a rate of **$83.89** per hour.