Feasibility Study
To Consider the Establishment of a Liver Transplant Institute

University of New Mexico Hospitals and
New Mexico Department of Health

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Based on report prepared by:

Transplant Management Group, LLC

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I. Overview

The 2013 legislative session passed House Memorial 48- Create NM Liver Transplantation Institute. HM 48 designated the NM Department of Health (DOH) and University of New Mexico Hospitals (UNMH) to conduct a feasibility study of a liver transplant center in New Mexico.

In March 2013 Representative Lundstrom convened a group of community partners to begin the response to HM 48. Members of that group consisted of interested community members, a DOH staff person, a local transplant surgeon and representatives from UNMH, Presbyterian and Lovelace Hospitals. The group met several times during 2013 and also presented testimony to the Legislative Health and Human Services Committee.

To accomplish the goal of conducting the feasibility study, a request for proposal (RFP) was prepared by DOH and UNMH staff and released in August 2013. Respondents were asked to respond to the following criteria:

- Proposed implementation,
- Staff and organizational experience,
- Performance assessment, data management and quality improvement,
- Knowledge of regulatory and organ sharing rules.

Five offerors were identified and contacted to inform them of the RFP. The organizations were Arbor Research, ECG Management Consultants, Hero Network LLC, Transplant Management Group, and Guidry and East. Additionally the RFP was published in the Albuquerque Journal.

Evaluation criteria for reviewing the responses were identified and points assigned:

Criteria	Points
• Background Information	10
• Qualifications and Capabilities	30
• Service Requirements	40
• Price Proposal	20
Total points	100

A panel consisting of personnel from DOH and UNMH reviewed the submitted proposals and awarded the contract for the feasibility study to Transplant Management Group (TMG) in October 2013. The feasibility study was funded entirely by UNMH.

II. Study Elements

TMG worked with DOH and UNMH to coordinate data gathering and plan a two-day review onsite at the hospitals identified as possibly housing a liver transplant program. The following hospitals were identified for the facilities review:

- University of NM Hospital, Albuquerque, NM
- Presbyterian Hospital, Albuquerque, NM
- Lovelace Medical Center, Albuquerque, NM (early in the site review, TMG was informed that Lovelace Medical Center would not be participating in the review).

TMG gathered data from various sources, including UNMH, Presbyterian Hospital, the Epidemiology & Response Division of DOH, the local Organ Procurement Organization and transplant-related organizations, both before and following TMG's onsite review. During their site visit on November 20– 21, 2013, they met with administrative, physician and nursing leaders, liver specialists and kidney transplant representatives both at UNMH and Presbyterian Hospital. TMG also met with abdominal transplant surgeon and NM liver transplant advocate, Julio Sokolich, MD.

The key components of the study included a market analysis, inclusive of liver transplant volume projections, and identification of program resource requirements. TMG provided a situation analysis with the following scenarios for consideration:

1. Free Standing Liver Transplant Institute with Liver Transplants Performed at the Free Standing Facility,
2. Liver Transplant Program in either PH or UNMH with Existing Kidney Transplant Programs,
3. Pre/Post Transplant Clinics in both PH and UNMH (status quo),
4. Free Standing Liver Transplant Institute with Local Collaborative Clinic for Outpatient Only Pre and Post Transplant Care,
5. National Partnerships/Collaborative Relationships with Selected Transplant Programs.

III. Factors Impacting Possible Liver Transplantation in NM

Liver transplantation is a complex topic is impacted by multiple factors including availability of organs, wait lists for transplants and the severity of illness in patients awaiting transplants. The scoring system used to rank patients needing liver transplants is called the Model for End-Stage Liver Disease (MELD). It is a numerical scale used for liver transplant candidates and ranges from 6 (less ill) to 40 (gravely ill). Each person is given a 'score'based on how urgently he or she needs a liver transplant within the next three months.

Recently a new allocation sequence called SHARE 35 began which provides broader access to those most in need of a liver (MELD higher than 35). Because the allocation methodology of livers changed to this broader sharing system, the competition for organs intensified. Instead of local organs being offered to local recipients first, the sickest patients with MELDS >35 will be given organ priority for the entire region.

NM is located in OPTN/UNOS Region 5 (Figure 1) which includes 4 of the largest programs in the nation. There are more transplants than deceased donor organs procured in this region which means this region is a net importer of livers. In Region 5, 33% of patients are being transplanted at MELD scores of 31 or greater and California is transplanting 50% of their patients at MELD scores of 31 or greater. This compares to national rates of 21% of patients being transplanted at MELD scores of 31 or greater. The anticipated result of the new Share 35 UNOS Regional liver allocation algorithm on Region 5 is that it will drive more organs to California due to the large waitlists with high MELD scores.

The Organ Procurement Organization in New Mexico is considered small covering 2 million in population. The significant issue with liver supply is the recent change in the liver allocation system to a more regionalized system that allocates the liver to the sicker patients regardless of where the liver donor is in the UNOS Region. This allocation change favors the large liver transplant programs and disadvantages the smaller volume liver transplant programs. This is particularly impactful to the smaller liver transplant programs in Region 5 as several of the country's largest liver transplant waiting lists are at transplant centers in Region 5.

Another factor impacting a potential liver transplant program is the wait list. In New Mexico, there are between 75 and 100 patients from NM on the wait list at other centers. Wait list size is critical to sustaining or growing a program in this competitive market with a wait list size greater than 125 to 150 patients needed to sustain a program.

Also to be considered is the history of liver transplantation in New Mexico. UNMH had a program from 1995 until 2000 when it was closed after the transplant surgeon left. The UNMH program closed soon after the implementation of the UNOS MELD score, which shifted the liver organ allocation to the sickest patients on the wait list.

IV. Situation Analysis

TMG prepared several situation analyses to review the critical factors in the feasibility of a new liver transplant institute or program in New Mexico by an assessment of the probabilities and barriers to success.

Five scenarios are presented:

Scenario A. Free Standing Liver Transplant Institute with Liver Transplants Performed at the Free Standing Facility,

Scenario B. Liver Transplant Program in either Presbyterian Hospital or UNMH with Existing Kidney Transplant Programs,

Scenario C. Pre/Post Transplant Clinics in both PH and UNMH (status quo),

Scenario D. Free Standing Liver Transplant Institute with Local Collaborative Clinic for Outpatient Only Pre and Post Transplant Care,

Scenario E. National Partnerships/Collaborative Relationships with Selected Transplant Programs.

For each scenario, five criteria are assessed:

1. Will NM have access to a population size to attain sufficient liver transplant volume for meeting regulatory requirements of ten (10) transplants per year as required by CMS?
2. Will NM have access to organs to sustain a liver transplant program?
3. Will NM have the financial resources to sustain the proposed scenario?
4. Will NM have the staffing and infrastructure to support the proposed type of facility?
5. Will the benefits outweigh the risks of this model?

Scenario A: Free Standing Liver Transplant Institute with Liver Transplants Performed at this Facility					
Probability of Success	**1 Very Poor**	**2 Poor**	**3 Average**	**4 Good**	**5 Excellent**
Will NM have access to a population size to attain sufficient liver transplant volume for meeting regulatory requirements of ten (10) transplants per year as required by CMS? **Comments/Barriers:** Only a limited number of patients would continue to leave the state for services because of insurance requirements.				x	
Will NM have access to organs to sustain a liver transplant program? **Comments/Barriers:** Organ donors continue to leave state. Share 35 results in 30% to 50% of organs leaving state. Regain 10 donors leaving state to increase sustainability. A large waitlist of 150 or more patients is the only way to gain access to more organs in the competitive market. Historically, this waitlist volume was never achieved in NM.		x			
Will NM have the financial resources to sustain a freestanding inpatient facility? **Comments/Barriers:** This would require a significant financial investment to add the comprehensive 24 hour support and a separate new or remodeled freestanding building.	x				
Will NM have the staffing and infrastructure to support a freestanding inpatient facility? **Comments/Barriers:** This would require extensive staffing and infrastructure support and duplication of services already provided in market.	x				
Will the benefits outweigh the risks of this model? **Comments/Barriers:** The investment in facility and staff make this option costly.	x				

Scenario B: Liver Transplant Program in either Presbyterian Hospital or UNMH with Existing Kidney Transplant Programs					
Probability of Success	**1 Very Poor**	**2 Poor**	**3 Average**	**4 Good**	**5 Excellent**
Will NM have access to a population size to attain sufficient liver transplant volume for meeting regulatory requirements of ten (10) transplants per year as required by CMS? **Comments/Barriers:** Only a limited number of patients would continue to leave the state for services because of insurance requirements.				x	
Will NM have access to organs to sustain a liver transplant program? **Comments/Barriers:** Organ donors continue to leave state. Share 35 results in 30% to 50% of organs leaving state. Regain 10 donors leaving state to increase sustainability. A large waitlist of 150 or more patients is the only way to gain access to more organs in the competitive market.		x			
Will NM have the financial resources to sustain a liver transplant program at one of the two hospital facilities? **Comments/Barriers:** The state would need to invest in the program at either hospital to make it successful and offset the initial investment requirements. Each hospital could contribute to the funding to support the program sharing the financial burden.			x		
Will NM have the staffing and infrastructure to support a liver transplant program at a local hospital that already has a kidney program? **Comments/Barriers:** This would require extensive staffing and infrastructure support. Presbyterian hospital reports lack of infrastructure and lack of desire to house liver transplant patients. UNMH lacks facility capacity in many key areas making adding new programs without adding facility space a major obstacle.		x			
Will the benefits outweigh the risks of this model? **Comments/Barriers:** The benefit in this model is less investment in a separate facility, not duplicating services and keeping financial support local. The risks are creating enough capacity at UNMH, funding the expenses of starting up the program, gaining access to sufficient organs and retaining professional talent short and long term			x		

Scenario C: Pre/Post Transplant Clinics in both Presbyterian Hospital and UNMH (status quo)					
Probability of Success	**1 Very Poor**	**2 Poor**	**3 Average**	**4 Good**	**5 Excellent**
Will NM have access to a population size to attain sufficient liver transplant volume for meeting regulatory requirements of ten (10) transplants per year as required by CMS? **Comments/Barriers:** No impact of population size.	n/a	n/a	n/a	n/a	n/a
Will NM have access to organs to sustain a liver transplant program? **Comments/Barriers:** NM residents compete in large patient pool for organs.	n/a	n/a	n/a	n/a	n/a
Will NM have the financial resources to sustain liver transplant availability to citizens of New Mexico? **Comments/Barriers:** The NM Medicaid program spends millions of dollars per year paying other states for liver transplant services. These costs are difficult to control or set limits as other states could choose to refuse to transplant NM patients. Presbyterian continues to fund out of state transplants through its insurance product.			x		
Will NM have the staffing and infrastructure to support pre and post care at each outpatient hospital based facility? **Comments/Barriers:** This would not require extensive changes to staffing or support but the expertise in liver transplant would not be available locally and identification of need for liver transplantation can be underserved or result in late referrals. Processes on transplant referral should be re-structured to improve patient pathway to transplant. Uniformity among the hospital systems would move this to a "Good" rating.			x		
Will the benefits outweigh the risks of this model? **Comments/Barriers:** The benefit in this model is no additional investment in facility or staffing but the risks are the expenses of offering liver transplant services outside the state of NM, escalating and limiting access to those citizens who cannot travel or bring 24 hour caregiver support out of state, or get referred too late for the lifesaving procedure.			x		

Scenario D: Free Standing Liver Transplant Institute with Local Collaborative Clinic for Outpatient Only Pre and Post Transplant Care					
Probability of Success	**1 Very Poor**	**2 Poor**	**3 Average**	**4 Good**	**5 Excellent**
Will NM have access to a population size to attain sufficient liver transplant volume for meeting regulatory requirements of ten (10) transplants per year as required by CMS? **Comments/Barriers:** No impact of population size.	n/a	n/a	n/a	n/a	n/a
Will NM have access to organs to sustain a liver transplant program? **Comments/Barriers:** NM residents compete in large patient pool for organs.	n/a	n/a	n/a	n/a	n/a
Will NM have the financial resources to sustain a freestanding outpatient facility? **Comments/Barriers:** This would require significant financial investment in a standalone facility.		x			
Will NM have the staffing and infrastructure to support a freestanding outpatient facility? **Comments/Barriers:** This would require separate staffing and infrastructure support and coverage of services already provided in market.		x			
Will the benefits outweigh the risks of this model? **Comments/Barriers:** The benefit is all patients receive comprehensive liver care in one location and expanding facility space. Expertise can be focused in this area. The risks are the initial and ongoing investment in providing duplicate services.		x			

Scenario E: National Partnerships/Collaborative Relationships with Selected Transplant Programs					
Probability of Success	**1 Very Poor**	**2 Poor**	**3 Average**	**4 Good**	**5 Excellent**
Will NM have access to a population size to attain sufficient liver transplant volume for meeting regulatory requirements of ten (10) transplants per year as required by CMS? **Comments/Barriers:** No impact of population size.	n/a	n/a	n/a	n/a	n/a
Will NM have access to organs to sustain a liver transplant program? **Comments/Barriers:** NM residents compete in large patient pool for organs in some states. May want to look at transplant programs located in areas with lower wait times than Region 5 with 100 or more waitlist size.	n/a	n/a	n/a	n/a	n/a
Will NM have the financial resources to develop a relationship with select few transplant centers? **Comments/Barriers:** The NM Medicaid program spends millions of dollars per year paying other states for liver transplant services. Leveraging these payments to only a select few hospitals could provide a mechanism to control costs while still providing services. Keeping pre and post services local when feasible will provide some additional in state revenue.				x	
Will NM have the staffing and infrastructure to support a national relationship with out of state transplant centers? **Comments/Barriers:** This would not require additional staffing or infrastructure. Pre and post follow-up services will need to be maintained locally.				x	
Will the benefits outweigh the risks of this model? **Comments/Barriers:** The benefit in this model is no additional investment in facility or staffing and gaining financial clout and consistency by selecting only a few programs to send patients to. The risks are the expenses of offering liver transplant services outside the state of NM, escalating and limiting access to those citizens who cannot travel or bring 24 hour caregiver support out of state, or get referred too late for the lifesaving procedure.				x	

III. Recommendations and Summary

As can been seen in the scenarios presented, scenario A of a stand-alone liver transplant institute had the lowest recommendation. Scenario B which is the addition of a liver transplant program to already existing kidney transplant programs also had a low recommendation. Scenario C which represents the status quo had an average recommendation. Scenario D, or a free standing coordination center/clinic collaborating with out of state liver transplant center, also did not have a good rating.

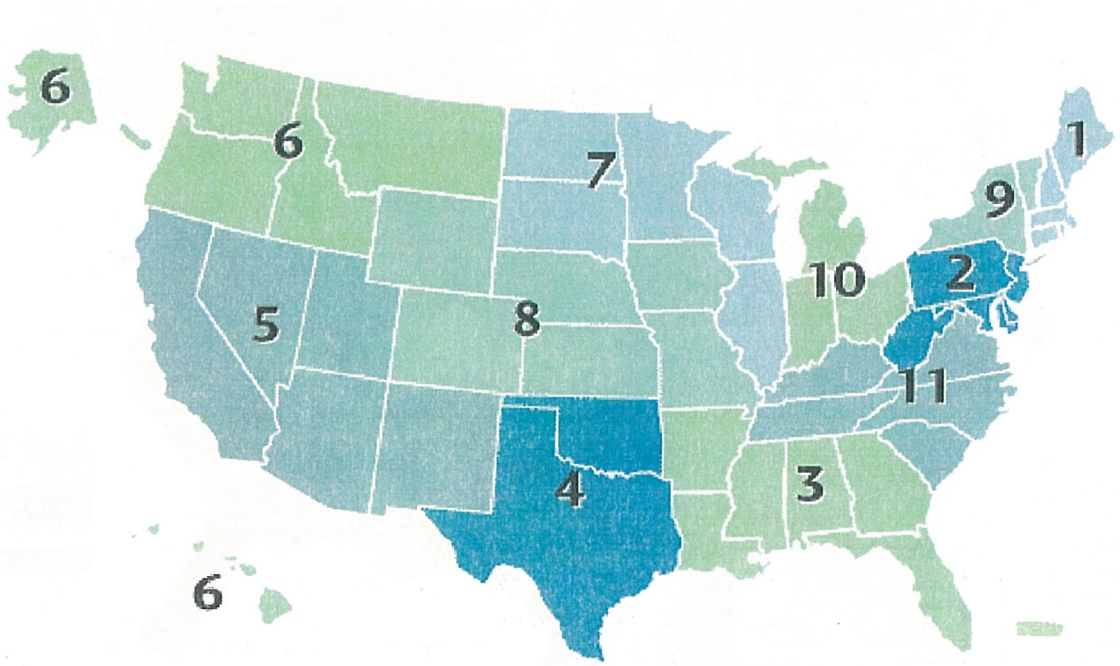
The scenario with the highest recommendation is E, the national partnership /collaborative relationship with an out of state liver transplant program. This scenario is modeled on the Veterans Administration (VA) system (see figure 2). VA Transplant Centers are located across the country and its network includes partnerships with multiple non-VA transplant centers around the country to provide comprehensive transplant services. The Veterans Administration typifies a successful national partnership model.

If a national partnership /collaborative relationship model is implemented in New Mexico, it would primarily impact patients insured through Medicaid since private insurers manage their own patients. Thus, not all New Mexicans needing liver transplants would be eligible for this system of care.

Advantages of establishing this type of national partnership /collaboration are many. It potentially would give patients needing liver transplants access to services in regions 4, 5, 8 (Figure 1). This would probably lower wait times for transplants. Both UNMH and Presbyterian hospitals already have liver care teams that serve both the pre and post liver transplant populations.

Medicaid could set up this type of system to leverage the resources we are already spending resulting in cost control, keeping pre and post transplant care local, and enhancing coordination of care which benefits our constituents.

Figure 1
List of OPTN/UNOS Regions



The states comprising each region are as follows:

- Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
- Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, Northern Virginia
- Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
- Region 4: Oklahoma, Texas
- Region 5: Arizona, California, Nevada, New Mexico, Utah
- Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, Washington
- Region 7: Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
- Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
- Region 9: New York, Western Vermont
- Region 10: Indiana, Michigan, Ohio
- Region 11: Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Figure 2
VA Transplant Centers