

How Reform Liver Allocation and Distribution.

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Factors to consider for UNOS for Liver Allocation.

The current proposal that was put forward by the Liver Intestine Committee “in keeping with the final rule”, chooses elimination of geographic barriers to transplant as the only strategy on which to base allocation. However, this is only one of many mandates defined in the final rule and is by no means, the sole prerogative of the policy issued by HRSA in 2000.

- The **final rule** (policy 121.8) states (in part) that organ **allocation shall be based on several variables, including:**
 - 1) **sound medical judgment;**
 - 2) the **best use of donated organs;**
 - 3) [to be] specific for each organ type or combination of organs to be transplanted into a specific candidate;
 - 4) [to be] designed to **avoid wasting organs, to avoid futile transplants, to promote patient access to transplant, and to promote efficient management of organ placement;**
 - 5) shall **not be based on the candidates place of residence or place of listing, except to the extent required by items listed above.**

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What appears missing is the incorporation of *all* the principles of the final rule into this allocation and distribution proposal and the principals of a well-defined policy strategy.

A framework of factors that should be included in creating of an Optimal Model and how it should be moved forward:

1. Increase organ donation/availability. Focus institutions and OPO's on increasing organ donation.

This will require a separate proposal from CMS which should include mandating the employment of best practices, optimal staffing and the use of standardized collection of meaningful potential organ donation rates.

2. Agree to an overarching allocation and distribution strategy.

We propose optimizing value delivered in liver transplantation by maximizing the 3 year patient outcome while minimizing the cost incurred to deliver that care. This is in contrast to the strategy of wait list removals of the sickest first in the redistricting proposals.

3a. Maximize Utility: Avoid transplanting cadaver organs too early when there is no demonstrated clinical benefit.

3b. Maximize Utility: Avoid transplanting patients with expected poor survival.

We have previously used 1 year 50% patient 1 year survival. Is it time to expect a 50 or 60% 3 year patient survival? The transplant community is responsible to the donors and their families that their donated organs are used responsibly. Factors requiring delisting need to be developed (example: 65 year old in ICU on pressors).

4. Update MELD, medical and exceptions.

HCC with no tumor blush on MR/CT post ablative therapy, should they be kept inactive until viable tumor can be documented?

5. Base the new allocation and distribution system on the assets we currently have or with minor additions.

With our proposal, the donor offer and placement would be handled by the current OPO covering the donor location.

6. Clean up our current system.

Only allow blood group identical donor-recipients.

Dis-allow non-resident transplant recipients (transplant tourists).

7. Limit the maximum distance between donor and recipient institution to some reasonable figure, example 500/450/400 miles from the donor hospital. (Radius of the Outer Circle)

Distribution areas of this significant size should be studied how they may even out the MELD score at which patients are transplanted in the US, but will not equalize it.

Or, create a population base of 30/40/50 million around the donor location. This is attractive as it would address the disparity of population density throughout the country.

8. Give local priority, to prevent unnecessary transportation, by adding 3-5 MELD point to recipients within a 300 /200 mile from the donor, the Inner Circle.

Local priority will help protect the disadvantaged rural population which dies from liver disease at higher rates than in urban centers, by helping local livers stay local. Local priority would also encourage local efforts to increase organ donation, ease logistical cost and resource wastage.

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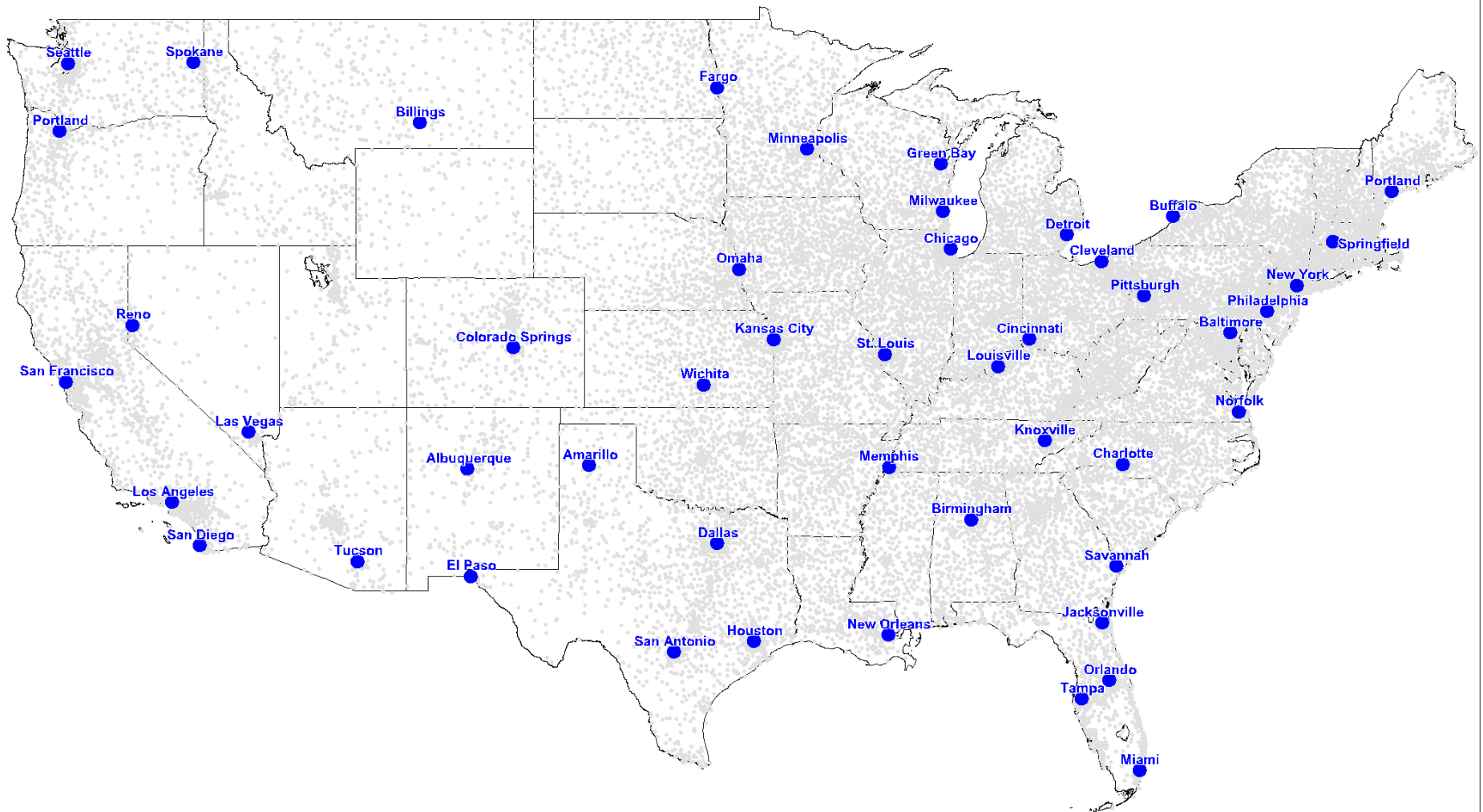
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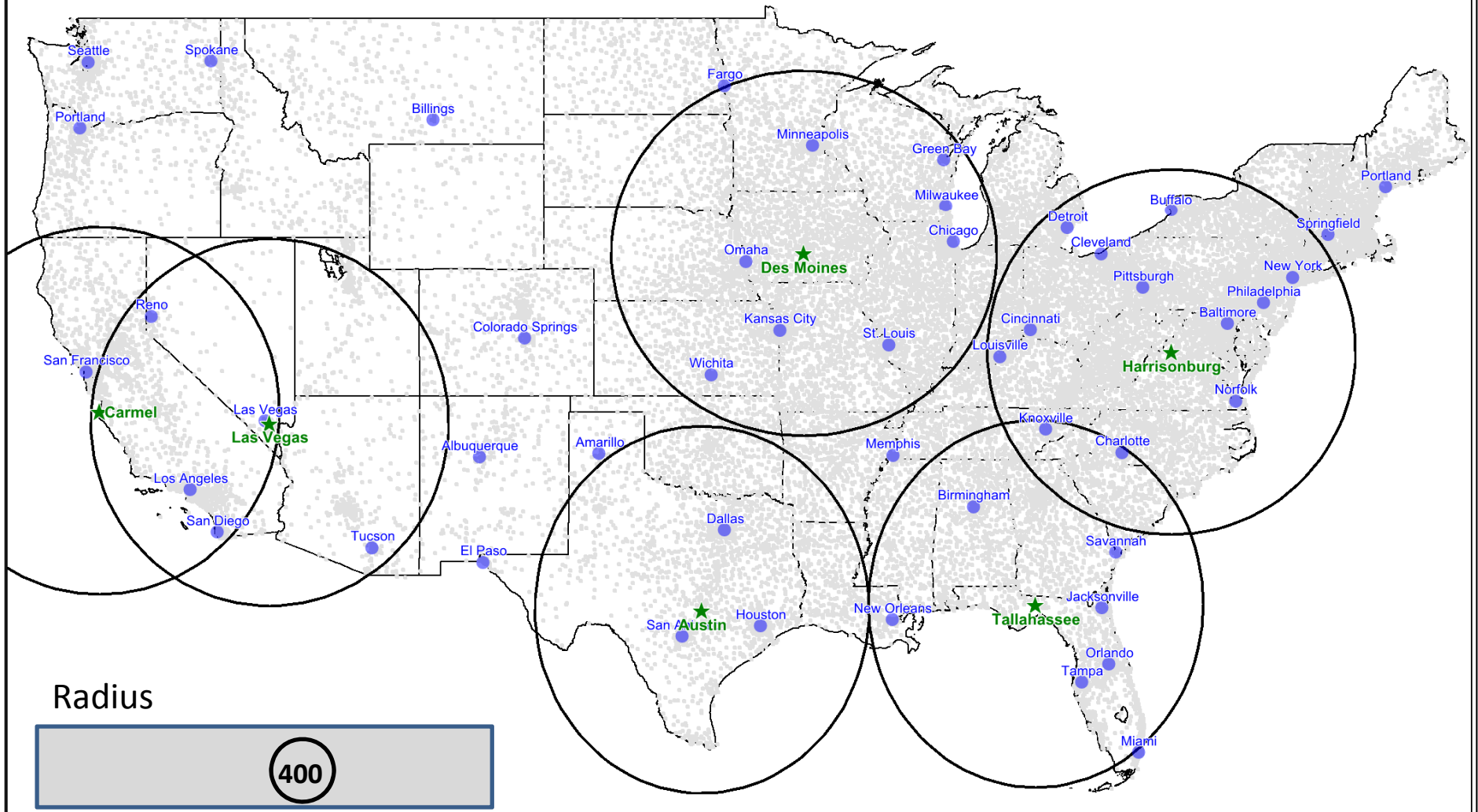
Summary: The advantages of the proposed system are:

- A system that is flexible for future changes
- Each distribution area will be large enough to even the medical MELD score at transplant while achieving the strategic goal.
- Avoid costly re-tooling our OPO and distribution system.
- Preventing added costs and needed resources compared to the current proposal.

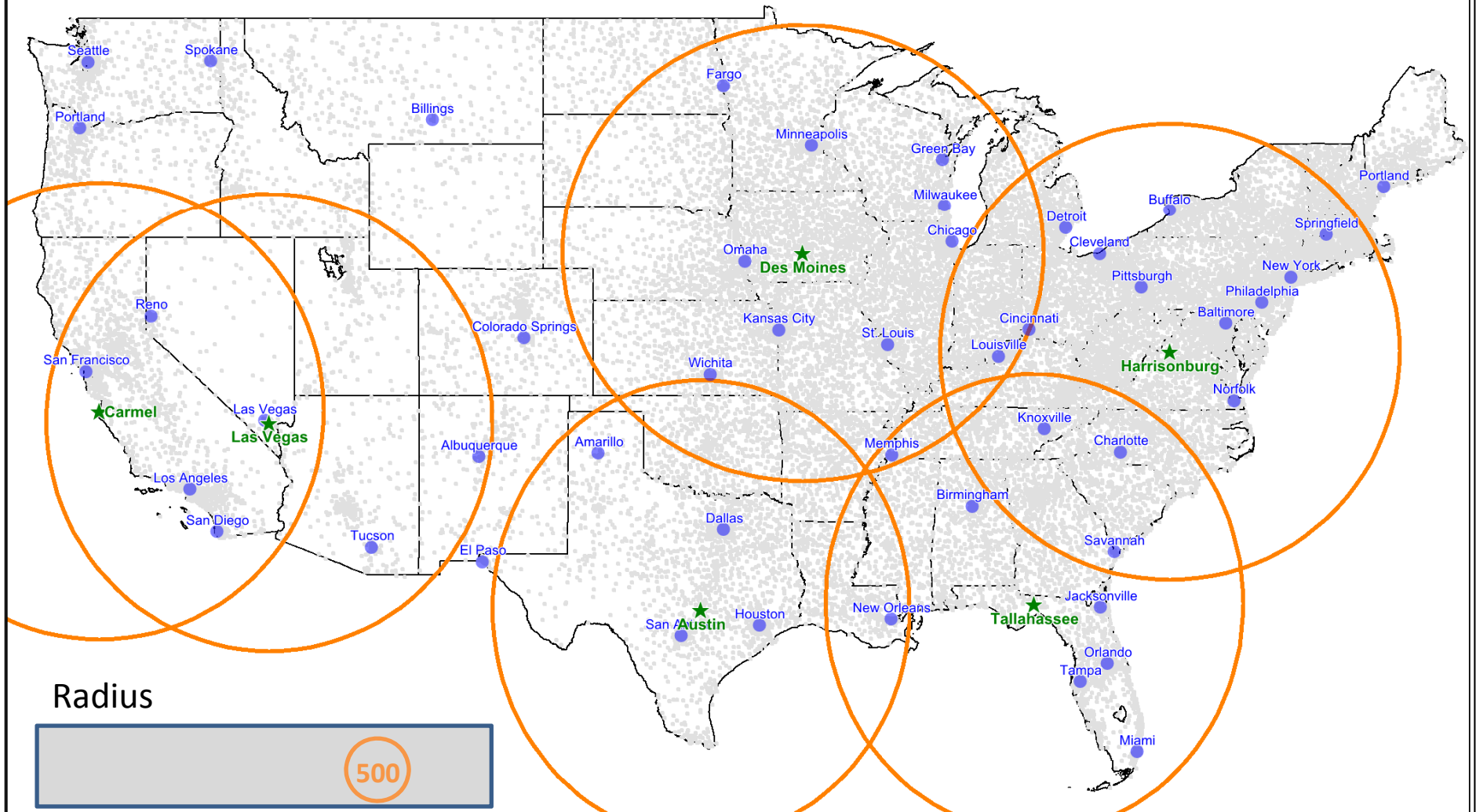
Continental US: Population and Major Cities



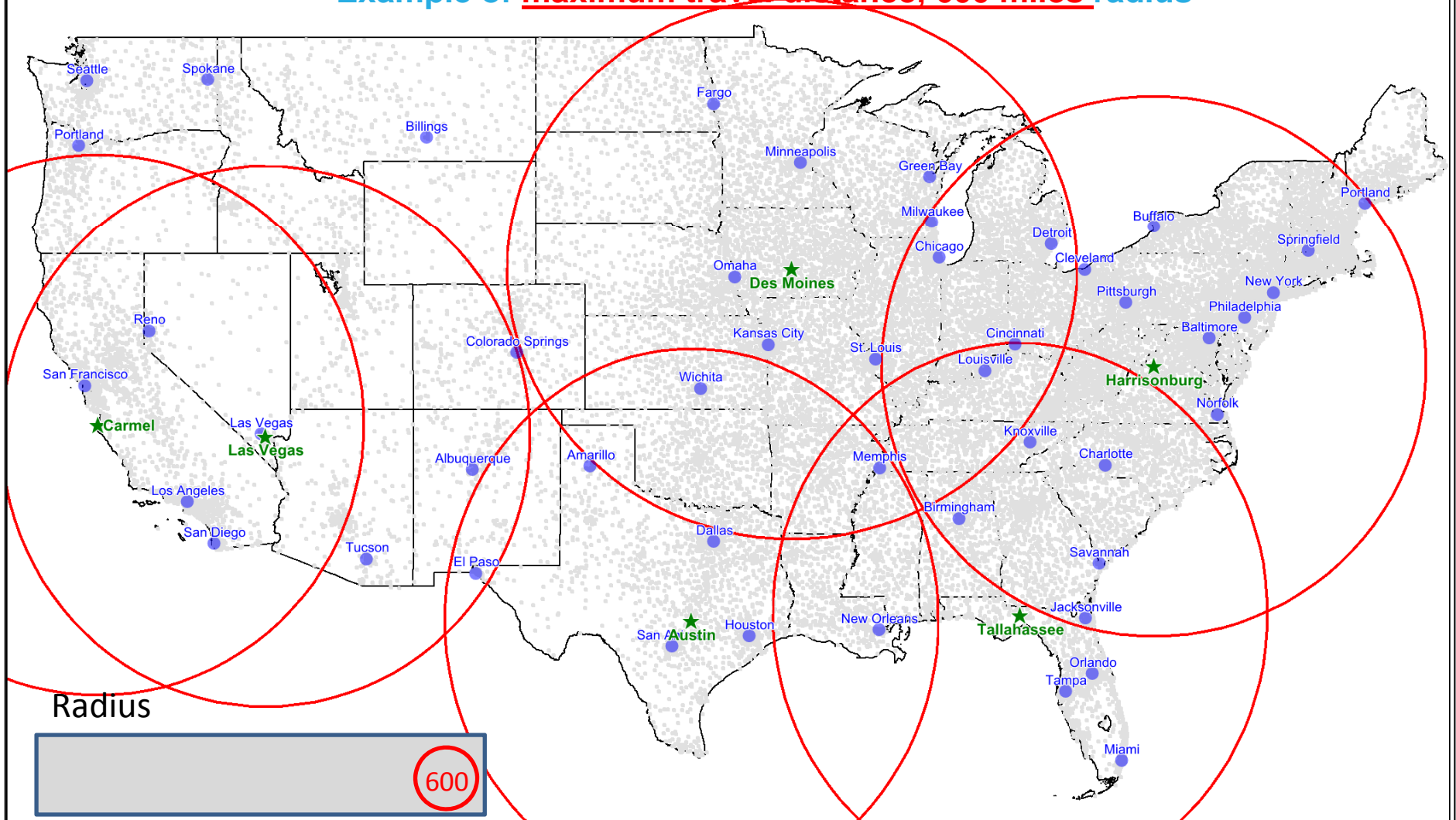
Continental US: **Donor Site Example Locations** and **Potential Distribution Area**
Example of maximum travel distance, 400 miles radius



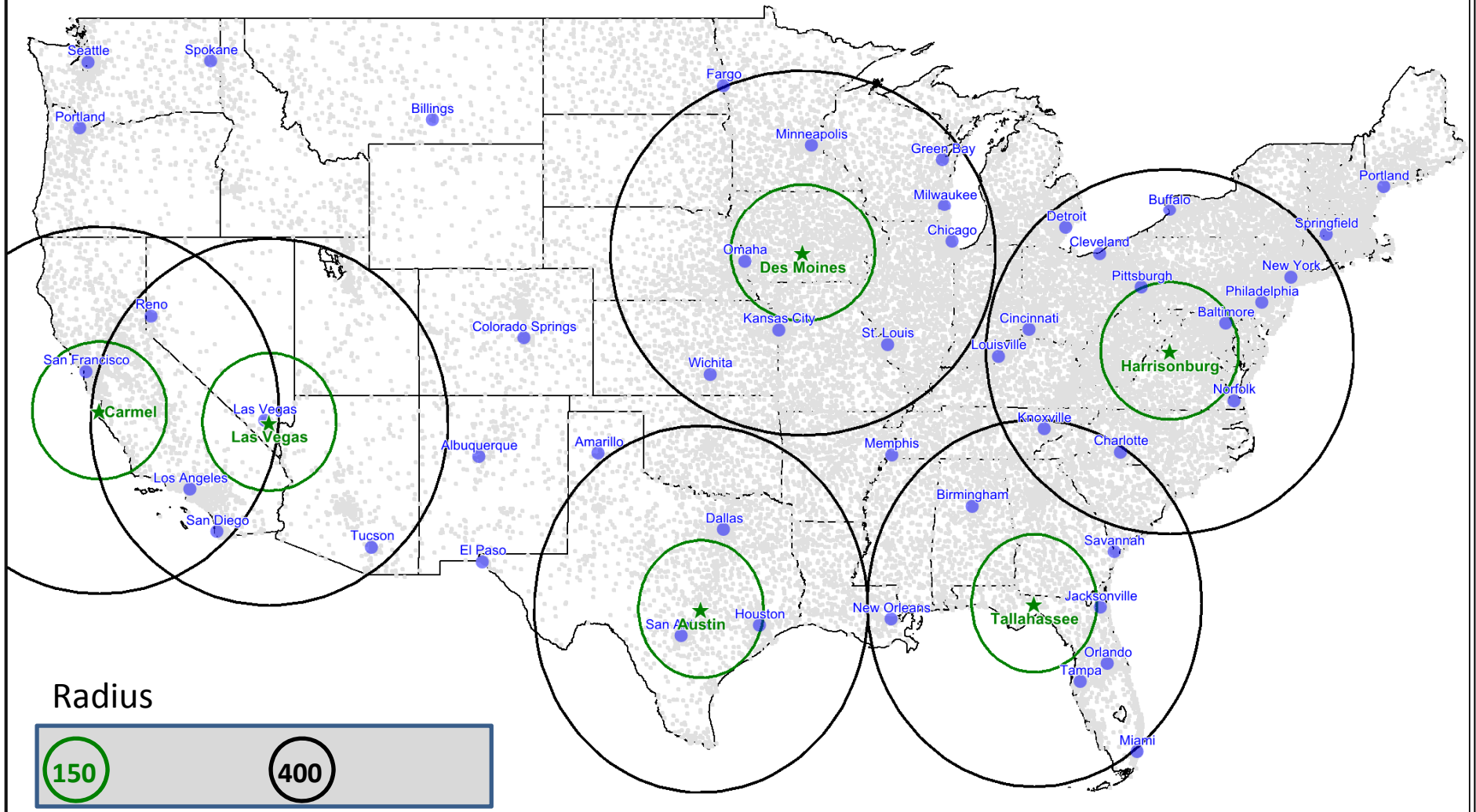
Continental US: **Donor Site Example Locations** and **Potential Distribution Area**
Example of maximum travel distance, 500 miles radius



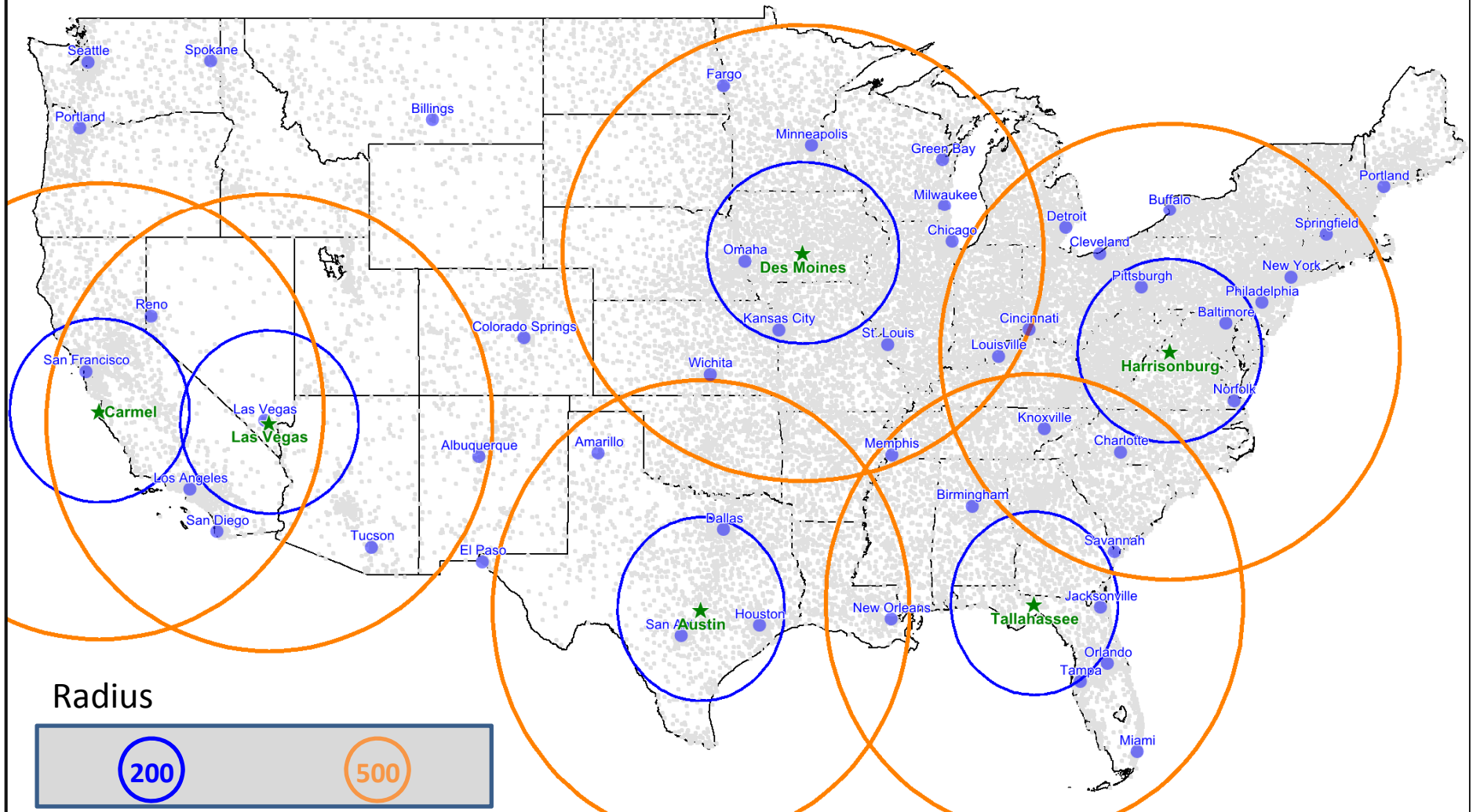
Continental US: Donor Site Example Locations and Potential Distribution Area
Example of maximum travel distance, 600 miles radius



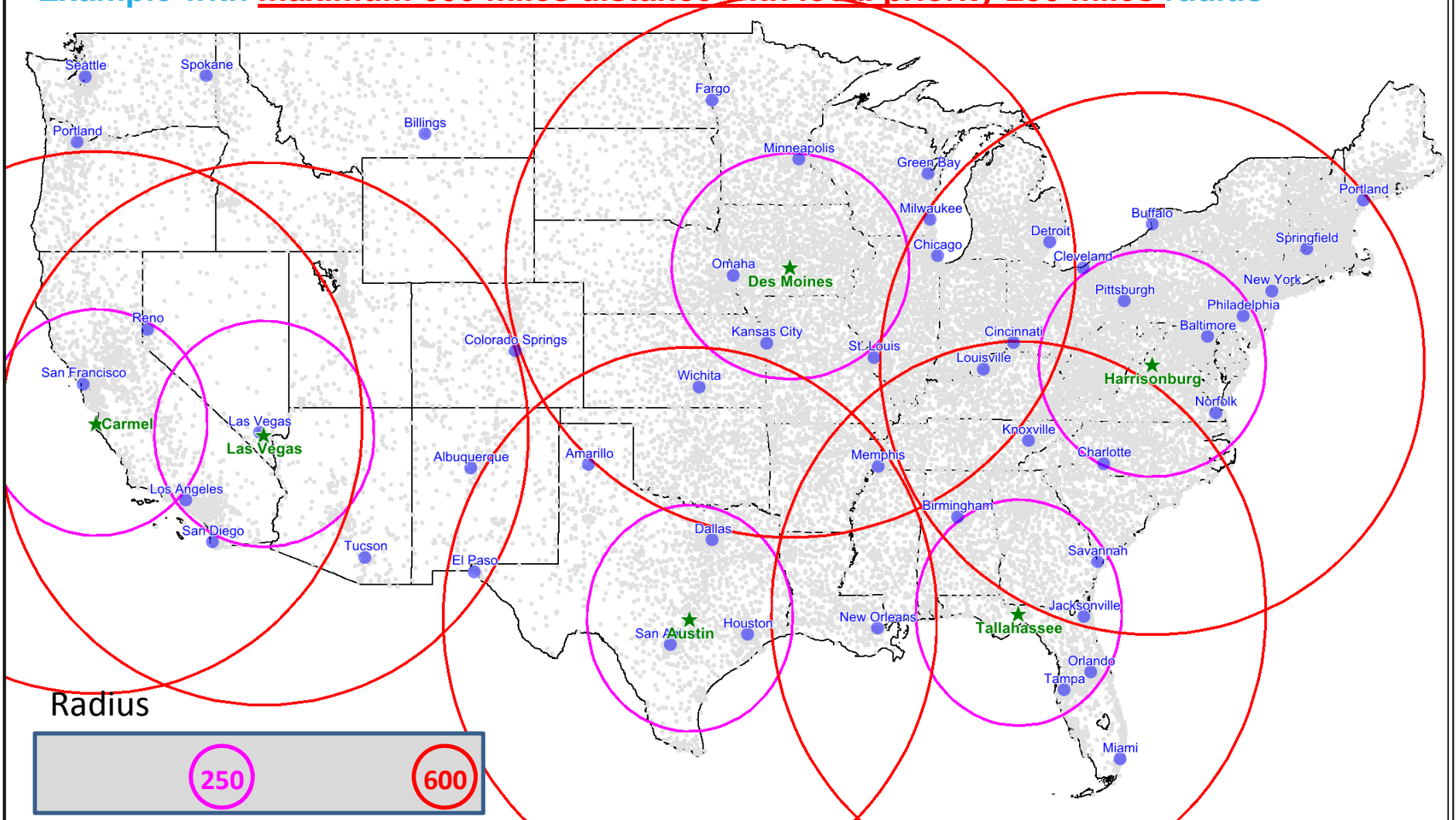
Continental US: Donor Site Example Locations and Potential Distribution Area
Example with maximum distance 400 miles with local priority 150 miles radius



Continental US: Donor Site Example Locations and Potential Distribution Area
Example with maximum distance 500 miles with local priority 200 miles radius



Example with maximum 600 miles distance with local priority 250 miles radius



Conclusions:

- 1. A new distribution system must make sense and be logistically doable.**

Cannot be based on current MELD; it will be updated making the proposal obsolete.

- 2. A new distribution system must be financially responsible.**

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3. **The proposed concentric circles have not yet been modelled as proposed and *should not be voted on until such time.***

Governmental Guidance

Limited by 2010 Appropriations Bill

“Any policy change on broader allocation of livers be tested first in demonstrations...”

“At least six months before any further change is implemented, OPTN must submit to the House of Representatives and the Senate a report analyzing and describing **the potential impact of any changes to broaden the geographic allocation of livers on the following:**

- (1) Access to transplantation for all patients at smaller volume transplant centers and who are listed at centers outside major urban areas;
- (2) Mortality of all patients on a waiting list at either smaller volume transplant centers or transplant centers located outside major urban areas;
- (3) Model for End-Stage Liver Disease (MELD) score at time of transplant;
- (4) Access to transplant and mortality rates;
- (5) Organ wastage rates;
- (6) One-year and three-year graft and patient survival, and total years prolonged by transplantation;
- (7) Ischemia time and function of the donor liver;
- (8) Transportation and other costs; and
- (9) Organ donation rates and public attitudes on organ donation .”