

March 13, 2013

Mr. Fritz Ruf  
W276N1905 Spring Creek Drive  
Pewaukee, WI 53072-5365



Dear Mr. Ruf,

I am a long-time Waukesha County resident and the Corporate Counsel for BloodCenter of Wisconsin (BCW). I am writing on behalf of BCW to express concerns related to a recent Bid/RFP process conducted by Waukesha County and a proposed contract. It is my understanding that the Judiciary & Law Enforcement Committee will discuss the proposed contract at its upcoming meeting on March 15, 2013. I would like to bring to your attention some significant legal issues related to the bid process and the proposed contract.

BCW is a Wisconsin, non-profit, tax-exempt organization that serves Wisconsin families in need of life-saving blood, organ and tissue transfusion and transplantation services. In addition to our donation center on Springdale Road, BCW partners with the Waukesha County Medical Examiner and currently provides organ and tissue donation services at all of the Waukesha County based hospitals. Working together, we ensure that Waukesha County residents seeking to share the gift of life through organ and tissue donation have access to high quality organ and tissue donation services. We value our relationship with the County and greatly appreciate your consideration of our concerns.

Waukesha County recently published a request for Bid/RFP # 13009 Tissue Donor Services, in which the County sought the highest bidder in exchange for tissue donor referrals from the Waukesha County Medical Examiner. The Bid/RFP changes the way that Waukesha has approached this process in the past, and creates a process that is substantially different from that used by other counties. The proposed contract is entitled, "**Waukesha County Contract No. \_\_ For Tissue Donor Referrals From the Waukesha County Medical Examiner.**" The highest bidder would receive "exclusive rights to donor referrals covered by this Contract and exclusive rights to use the Facilities for tissue recovery in County Referred Cases."

While in most cases it is appropriate for the County to seek the highest bidder in order to raise the most funds for public purposes, the "highest bidder" approach is unlawful in this context. As a matter of state and federal law, the County is not permitted to make a profit from human tissue donations. Moreover, the County has not followed a number of statutorily required procedures in the recent bid process. There are three different legal issues that need to be addressed:

1. The proposed award and tissue donor referral contract provides for valuable consideration in exchange for tissue donor referrals, in violation of federal and state statutes that make it unlawful to acquire, receive or otherwise transfer human tissue in exchange for valuable consideration;

2. The County is allowed to recover its costs in participating in the process of human tissue donation, but the County failed to comply with Wis. Stat. § 59.36 and Wis. Stat. § 59.38, which require the County Board to (i) set fees charged by coroners and medical examiners; and (ii) ensure that such fees are limited to an amount that is reasonably related to the actual and necessary cost of providing services; and
3. During the evaluation process, the County failed to request and consider information about potential service providers as required by Wis. Stat. § 157.06 (24m).

In the remainder of this letter I will provide you with some brief background information, references to the relevant state and federal statutes, and further facts that show that the contract being considered by the County is unlawful.

## **Background**

First, let me provide a short description of how organ and tissue recovery became a part of BCW's charitable mission, and explain how BCW operates as an accredited "tissue bank." Prior to February of 2009, the Wisconsin Tissue Bank (a tissue procurement organization) was owned and operated by Aurora St. Luke's Medical Center, and Wisconsin Donor Network (a federally designated organ procurement organization) was owned and operated by Froedtert Memorial Lutheran Hospital. Aurora and Froedtert operate organ and tissue transplantation programs and concluded that their respective patients and providers would benefit if organ and tissue donation and recovery services were performed by a single, unrelated third party. The Chief Executive Officers of Aurora and Froedtert approached BCW and asked whether BCW would be willing to accept the simultaneous transfer of both programs. BCW has played an essential role in transfusion and transplant medicine for many years. Thus, BCW concluded that the programs were consistent with its charitable mission and agreed to accept the programs. In February 2009, the Wisconsin Tissue Bank and the Wisconsin Donor Network became part of BCW. As a result, BCW is now both a federally designated OPO and an accredited tissue bank.

As an American Association of Tissue Banks (AATB) accredited tissue bank, BCW facilitates tissue donation by performing a number of critical functions. First, BCW promotes life-saving organ and tissue donation within our community by providing education to local health care providers and community outreach. BCW also maintains a staff of highly trained "designated-requestors" who are on call 24/7 to go to area hospitals, meet with potential donor families, provide education, and answer questions about organ and tissue donation.

If an individual has already expressed his or her intent to be a donor, or family members express an interest in donation, our staff collect essential medical records, coordinate necessary infectious disease testing, and ensure that donor families are supported and adequately informed before authorizing tissue donation. BCW personnel also coordinate and perform tissue recovery. Tissue recovery and banking are highly regulated by the U.S. Food & Drug Administration (FDA), and BCW personnel follow carefully constructed tissue recovery and preservation policies that maximize the potential of each individual donor's gift and ensure

compliance with federal requirements and accreditation standards. Following donation, BCW staff provide ongoing family support and recognition.

Medical Examiners, including the Waukesha County Medical Examiner, play a role in facilitating tissue donation by referring potential donors to one or more qualified tissue banks and providing access to copies of necessary medical information. There are two types of potential tissue donors whose remains come under the jurisdiction of a County Medical Examiner: individuals who have died in a hospital, and individuals who have died outside a hospital. Under state law, potential donors who have died in a hospital must be referred by the Medical Examiner to the tissue bank which is under contract with the hospital, regardless of whether the remains come under the jurisdiction of the Medical Examiner. The bid process and contract currently under consideration does not affect these types of potential donors.

For potential donors who have died outside of a hospital, however, the situation is different. The Medical Examiner may refer potential donors to any authorized tissue bank under contract with the County, provided that the requirements of Wis. Stat. § 157.06(24m)(b) are satisfied. For the purposes of the discussion below, I will refer to such donors as “County-referred tissue donors.” It is important to understand in this regard, however, that because of the sensitivities surrounding organ and tissue donation, it is not legally permissible for entities such as the County to raise revenue or otherwise seek valuable consideration in exchange for organ or tissue donor referrals.

As briefly noted above, Waukesha County recently published a request for Bid/RFP # 13009 Tissue Donor Services, in which the County sought the highest bidder in exchange for County-referred tissue donors from the Waukesha County Medical Examiner. The proposed contract is entitled, **“Waukesha County Contract No. \_\_ For Tissue Donor Referrals From the Waukesha County Medical Examiner.”** The highest bidder would receive “exclusive rights to donor referrals covered by this Contract and exclusive rights to use the Facilities for tissue recovery in County Referred Cases.” The minimum bid was set at \$60,000.00 and tissue banks could elect to use County facilities for tissue recovery, or forgo the use of County facilities and transfer tissue donors to another facility for recovery. Respondents were required to be accredited by the American Association of Tissue Banks (AATB), but no additional information (such as history of FDA regulatory compliance or FDA warning letters) were requested.

## **Legal Issues**

The recent bid process and the proposed contract are problematic because they are inconsistent with applicable federal and state laws. First, the “highest bidder” contracting process violates state and federal law prohibiting the payment of valuable consideration in return for the referral of human tissue donors. Under the National Organ Transplant Act, Public Law 98-507 (NOTA), it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. 42 U.S.C. § 274e provides as follows:

**42 U.S.C. § 274e. Prohibition of organ purchases**

- (a) Prohibition. It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.
- (b) Penalties. Any person who violates subsection (a) of this section shall be fined not more than \$50,000 or imprisoned not more than five years, or both.
- (c) Definitions. For purposes of subsection (a) of this section:
  - (1) The term “human organ” means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.
  - (2) The term “valuable consideration” does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

Wisconsin Statute § 146.345 closely mirrors the federal requirements set forth under NOTA, adding only compensation of a living human organ donor’s costs related to travel, housing and lost wages:

**Wis. Stat. § 146.345 Sale of human organs prohibited.**

- (1) In this section:
  - (a) “Human organ” means a human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone or skin or any other human organ specified by the department by rule. “Human organ” does not mean human whole blood, blood plasma, a blood product or a blood derivative or human semen.
  - (b) “Human organ transplantation” means the medical procedure by which transfer of a human organ is made from the body of a person to the body of another person.
  - (c) “Valuable consideration” does not include reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control or storage of a human organ or an expense of travel, housing or lost wages incurred by a human organ donor in connection with donation of the human organ.
- (2) No person may knowingly and for valuable consideration acquire, receive or otherwise transfer any human organ for use in human organ transplantation.
- (3) Any person who violates this section is guilty of a Class H felony, except that, notwithstanding the maximum fine specified in s. 939.50 (3) (h), the person may be fined not more than \$50,000.

The federal and state statutes make it clear that Waukesha County cannot seek valuable consideration for the referral of tissue donors. The County may only be reimbursed

for its costs incurred in aiding the tissue bank in the donation. Costs that the County can appropriately recover are limited to those related to actual and reasonable expenses incurred by the County in relationship to the following:

1. Removal
2. Transportation
3. Implantation
4. Processing
5. Preservation
6. Quality control
7. Storage of a human organ;
8. Expense of travel, housing or lost wages incurred by a human organ donor in connection with donation of the human organ

Under the process currently being followed by the Waukesha Medical Examiner, the County is not involved in any of the activities associated with items 2-8. As a result, the County can only seek to recover fees related to services it provides with respect to removal of the tissue.

In addition, to the extent that the Medical Examiner provides services relating to removal of tissue, then, as set forth below, the fees for those services must be set by the County Board under Wisconsin Statutes § 59.36 and § 59.38. Under Wis. Stat. § 59.36, the Waukesha County Board is required to establish fees for all services rendered by the coroner and *such fees may not exceed an amount that is reasonably related to actual and necessary costs of providing the service.* Thus, in order to be reimbursed for the expenses incurred by the County in its participation in the tissue donation process, the County must identify what services it is providing (within the eight categories defined above) and a fee must be set for those services that is equal to the County's cost.

The highest bidder process utilized by the County with respect to Bid/RFP #13009, is inherently incompatible with the federal and state laws prohibiting the exchange of valuable consideration, and state laws requiring the County Board to establish fees that do not exceed costs. The County Board did not establish fees for any services actually provided by the Medical Examiner or ensure that such fees were "reasonably related to actual and necessary costs of providing service." Rather, the County offered to exchange an exclusive right to donor referrals (and use of County facilities) for the highest bid. Under the law, the County is limited to recovering any expenses it actually incurs as part of its involvement in the donation process.

Notably, the contract proposed by the County included a minimum annual fee of \$60,000.00, regardless of facility use. Therefore, it is not a defense to these statutes to contend that the contract at issue does not involve the transfer of human organs but is instead a contract to use County facilities. The title of the contract makes it clear that the contract is for

“Tissue Donor Referrals” and, of course, the purpose of the contract is to facilitate the Waukesha County Medical Examiner’s role in the human tissue donation process.

Finally, as noted above, the Medical Examiner may only refer County-referred tissue donors to a tissue bank if the requirements of Wis. Stat. § 157.06(24m)(b) are satisfied. These requirements are as follows:

- The coroner or medical examiner, after considering a tissue bank's history, services, traditional referral patterns, geographic service area, and tissue distribution record and any other criteria required for consideration by the corporation counsel of the applicable county, enters into a written, general referral agreement with one or more tissue banks to which the coroner or medical examiner shall refer decedents for potential donation of tissue.
- The tissue agreement between the coroner/medical examiner and the tissue bank is subject to review and approval of the county’s corporation counsel and the county board (unless the Board declines to review).
- The tissue bank is accredited by the American Association of Tissue Banks or audited at least once every 2 years by an organization that is accredited by the American Association of Tissue Banks.

The process utilized by the County with respect to Bid/RFP 13009 did not satisfy these requirements. None of the information which the Medical Examiner was required to consider under the first requirement of Wis. Stat. § 157.06(24m)(b) was requested from the bidders. This means that the Medical Examiner cannot perform the due diligence which is required by law.

**Request for Reconsideration**

In light of the above, we respectfully request that the Waukesha County Board reform the Bid/RFP process and re-issue its request for proposals. We suggest the following process:

1. In accordance with Wis. Stat. § 59.36 and 59.38, the Waukesha County Board should identify the services provided by the Medical Examiner during the tissue donation process and establish reasonable and necessary fees for services that do not exceed an amount that is reasonably related to the actual and necessary cost of providing the service. Because a tissue bank may elect to transport a potential donor off-site, we recommend two separate per-donor fees, one that includes use of County facilities during recovery, and one that does not. For example:

<p style="text-align: center;"><b>Tissue Donation Services</b> (Off-Site Recovery by Tissue Bank)</p> <ul style="list-style-type: none"> <li>• preparation of copies of necessary records</li> </ul>	<p style="text-align: center;"><b>Tissue Donation Services</b> (On-Site Recovery by Tissue Bank)</p> <ul style="list-style-type: none"> <li>• preparation of copies of necessary records</li> <li>• short-term use of a recovery room (approximately __ hour per donor)</li> <li>• cleaning supplies</li> </ul>
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	<ul style="list-style-type: none"><li>• biohazardous waste disposal</li><li>• if County staff attend an on-site recovery, personnel time for County staff</li></ul>
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2. The Waukesha County Board should re-issue the Bid/RFP at the established cost and request that respondents provide the information necessary to evaluate the history and performance of the tissue banks in accordance with Wis. Stat. § 157.06(24m)(b).

Again, thank you for your time and willingness to consider the concerns described above. I plan to be present at the Judiciary & Law Enforcement Committee meeting on March 15, 2013 and would be happy to answer any questions you may have about any of the above. BCW has long-standing relationships with many Medical Examiners in Southeast Wisconsin and we hope to be able to continue our relationship with the Waukesha County Medical Examiner.

Very Truly Yours,



Maureen Kwiecinski  
BloodCenter of Wisconsin, Inc.  
Corporate Counsel